CONCENTRATED PLATELET RICH PLASMA (cPRP) SYSTEM

Angel® Concentrated Platelet Rich Plasma (cPRP) System - Operator's Manual

Software Version 1.21

966030107 Rev. E

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Before You Get Started

Introduction

The *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System (Angel)* is designed to separate autologous blood or a mixture of blood and bone marrow. The primary blood components that the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System* separates and collects are red blood cells (RBC), platelet poor plasma (PPP) and platelet rich plasma (PRP).

The *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System* utilizes a variable volume separation chamber that is capable of processing between 40 ml - 180 ml of anticoagulated whole blood or mixture of blood and bone marrow in a single cycle. A total of 180 ml can be processed over three (3) cycles per disposable.

This manual is intended for users of the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System*. The procedures recommended in this Operator's Manual have been developed and tested to provide safe, reliable and efficient operation of the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System*. It is important that the operator thoroughly understand the information in this Operator's Manual before attempting to use the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System*.

Indications for Use

The *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System* is intended to be used in the clinical labaratory or interoperatively at the point-of-care for the safe and rapid preparation of platelet poor plasma and concentrate (platelet rich plasma) from a small sample of whole blood or a small mixture of blood and bone marrow. The platelet rich plasma from the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System* can also be mixed with autograft and/or allograft bone prior to the application to an orthopedic site.

Disclaimer

Platelet Rich Plasma prepared from a mixture of whole blood and bone marrow may contain higher levels of plasma free hemoglobin than Platelet Rich Plasma prepared from whole blood.

Contraindications for Use

The *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System* may be contraindicated in cases where there is active systemic infections or systemic heparinization.

Warnings

1. The use of operating or maintenance procedures other than those published by Cytomedix, Inc., or the use of accessory devices not recommended by Cytomedix, Inc. may result in poor equipment performance.

   Cytomedix, Inc. will not be responsible for patient safety or equipment performance if the procedures to operate and maintain the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* are other than those specified by Cytomedix, Inc. Persons performing the procedures must be properly trained and qualified.

   Any equipment modifications must be performed by qualified persons and be approved by Cytomedix, Inc. in writing.

   All electrical installations must comply with all applicable local electrical codes and Cytomedix, Inc. specifications.

   This equipment meets the following standards in the United States and the user does not need to provide additional efforts regarding electromagnetic emissions or immunity:

   - EN 55011, Class A standards (for electromagnetic emissions)
   - EN 61000 (for electromagnetic emissions)
   - IEC 60601-1-2 (2007) (for electromagnetic immunity)
   - Canadian Warning: This equipment is intended for use by healthcare professionals only. The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* or shielding the location.

2. The operator should never touch the data port on the *Angel® cPRP System*, while at the same time making contact with the patient, as potential for electrical shock may result.

3. Place the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* on a flat, stable surface. Never try to move the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* while the device is in operation. Failure to comply may result in damage to the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* and injury may result.

4. Do not use the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* in the presence of flammable agents because an explosion and/or fire may result.

5. A trained operator should be present at all times to operate and monitor the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* during processing.

6. Do not contact any moving parts of the centrifuge or pump while the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is in operation. Injury may result.

7. To prevent risk of electrical shock, do not use alternate power plugs or adapters that disconnect the safety ground.

8. Only *Angel® cPRP Processing Set*s are approved for patient use with the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*.

9. Do not use the *Angel® cPRP Processing Set* if the sterile packaging barrier has been broken.

10. Carefully examine the *Angel® cPRP Processing Set* for damage prior to use. Should any evidence of damage to the Processing Set be evident, do not use the Processing Set.

11. Carefully observe the *Angel® cPRP Processing Set* for leaks during use. Leakage may result in loss of sterility of the device or loss of blood product.

12. Use of this product for pediatric patients is at the discretion of a physician. Blood withdrawal from a pediatric patient should be performed in the presence and at the direction of a physician to prevent significant reduction of the circulating blood volume.

13. When collecting and processing autologous blood products it is recommended that the following precautions be followed to insure that the autologous product is not contaminated:

    - Use sterile technique when setting up the *Angel® cPRP Processing Set*
    - Thoroughly clean and disinfect the donation site
    - Use sterile technique whenever handling autologous blood products

14. The whole blood or the mixture of blood and bone marrow must be anticoagulated before it can be processed for separation. Inadequate anticoagulation may result in clotting, interfering with the processing of the blood products. Blood containing clots will not pass through the syringe-activated valve located on the Whole Blood compartment of the three-compartment reservoir bag.

15. Failure to properly load the centrifuge plate prior to processing may lead to exposure to blood and blood-borne pathogens.

16. If centrifugation is discontinued before the completion of a processing cycle, the variable volume separation chamber is pressurized and presents the risk for exposure to blood and blood-borne pathogens if the variable volume separation chamber is not properly removed. Please refer to “Stop Button” on page 3-27 for emptying a variable volume separation chamber containing blood.

17. If a power loss occurs, and there is blood or a mixture of blood and bone marrow in the variable volume separation chamber, follow the instructions under “Power Loss” on page 3-28.

18. Failure to properly secure the luer lock syringe to the valve assembly may result in a leakage of fluids.

19. Do not directly connect the patient to the three-compartment reservoir bag. Direct connection to the patient could lead to vascular damage, shock, or air embolism.

20. Disposal of used equipment and/or used *Angel® cPRP Processing Set*s should be in accordance with federal, state, and local regulations. These materials should be considered biohazardous. Universal precautions for blood-borne pathogens should be practiced when disposing of these items.

21. Do not place objects in pump during pump rotation. Damage to machine and disposable may result.

22. Do not use the separated blood products if the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* fails to operate as intended.

23. The platelet rich plasma is not intended for transfusion.

Warnings (Cont.)

24. The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is not intended to be used directly by the patient. As such a mains power switch is not available to the user. In case of an emergency, power from the unit can be removed by unplugging the unit from the electrical socket.

25. Only devices or cables meeting IEC 60950 should be connected to the USB and/or Ethernet port. Failure to do so may result in operator shock. All cables used in conjunction with the device should be no longer than 1m (3ft) in length.

Precautions

1. Carefully read this Operator's Manual for complete instructions.

2. This product is intended for use by trained medical personnel only.

3. When cleaning the platelet sensor, do not use bleach, abrasive materials or solvents as they may cause damage to the sensor. Use a mild detergent.

4. Do not place external light sources within 1 meter (3 feet) of the unit when operating the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*. External light sources may interfere with the operation of the platelet sensor and may result in reduced processing efficiency.

5. Do not immerse the pump rotor in cleaning solution. Do not autoclave. Component damage may result.

6. Prior to first use follow the installation instructions included in this manual.

7. Any device connected to the data port must comply with the applicable IEC standard for that device.

8. To prevent risk of electrical shock, shut OFF power and unplug the system from the electrical outlet before performing cleaning procedures or replacing the fuses.

9. Report immediately to the Cytomedix, Inc. Customer Service Response Center any of the following conditions. Do not use the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* until corrective action has been taken:

    - Damaged or worn power cord, plug or receptacle
    - Switches that are loose or do not operate with a positive action
    - A system that has been subject to significant physical damage
    - A system that has given anyone an electrical shock while in use
    - A system that appears to be overheating

10. It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood-borne infectious diseases.

11. Due to the possibility of operator exposure to blood-borne pathogens (such as HIV, hepatitis viruses, bacteria, etc.), Universal Precautions for blood-borne pathogens should be practiced.

12. The *Angel® cPRP Processing Set* is intended for single patient use. Each set can be used on the same patient for up to three processing cycles. Do not resterilize any part of this Processing Set.

13. Failure to properly load the *Angel® cPRP Processing Set* per the enclosed instructions may affect the performance of the system.

14. Luer lock syringes should be used with the *Angel® cPRP Processing Set*.

15. Pressing the Stop button during separation may reduce processing efficiency.

16. The physician ordering the collection of PRP shall use discretion when any of the following conditions exist:

    - sepsis
    - preoperative hematocrit less than 30%
    - preoperative platelet count less than 195,000 per ul
    - hemodynamically unstable
    - prolonged clotting times
    - recent use of anti-platelet drugs
    - inability to maintain stable oncotic pressure

17. Attach the power cord only to a power receptacle which is properly grounded.

18. Replace the mains fuses only with fuses of the same type and rating.

19. There are no user-serviceable parts inside this device. To avoid the risk of electrical shock, do not remove the cover. Refer all servicing to qualified service personnel.

20. Take care not to misplace the screws and springs when disassembling the centrifuge adaptor plate. If springs or screws are misplaced, you may order replacements by contacting Cytomedix, Inc.

21. Federal law (USA) restricts this device to sale by or on the order of a physician.

22. The user of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is responsible for the monitoring of the system performance when using custom protocols.

23. The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* has been tested and verified to meet applicable Electromagnetic Compatibly (EMC) and Electrical Safety standards when used in conjunction with the specified Data Integrity Accessories. (Refer to Section 6.)

24. The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* has the ability to save data using both the USB and Ethernet Network connections. When using either of these connections, it is recommended that the applicable Data Integrity Accessory be used. (Refer to Section 6.)

Symbols and Certifications

If applicable, the following symbols may appear on the device labeling.

REF — Catalog number.

MODEL — Model number.

Attention. Consult accompanying documents. (IEC 60601-1, 2nd Edition)

Caution. (IEC 60601-1, 3rd. Edition)

Follow instructions for use.

Date of manufacture.

This symbol indicates that the device requires an alternating supply current.

This symbol identifies the point of connection of a potential equalization conductor. The location of this connection point is at the rear of the machine, below the access door.

This symbol indicates the power OFF position on the main power switch.

 This symbol indicates the power ON position on the main power switch.

Manufacturer.

Rx ONLY — Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

SN — SN Serial number.

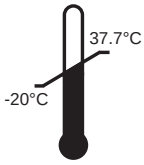
This symbol specifies the type of fuse(s).

To reduce the risk of electrical shock, do not remove cover. There are no user-serviceable parts inside. Refer servicing to qualified service personnel.

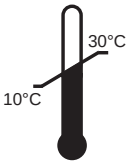
This side up

Fragile

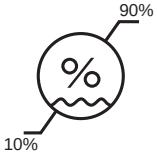
Keep dry



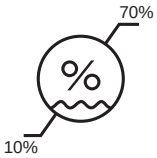
Ship and store between these temperatures: -20 and 37.7 degrees C (-4 and 100 degrees F).



Install and operate between 10 and 30 degrees C (50 and 86 degrees F).



Ship and store between 10% and 90% relative humidity.



Install and operate between 10% and 70% relative humidity.

Service Information

The company accepts responsibility for the safety, reliability and performance of this equipment only if operational procedures, calibrations and repairs are performed by appropriately qualified persons; if all equipment modifications are authorized in writing by the company and performed by appropriately qualified persons; if the electrical installation of the relevant room complies with all applicable local electrical codes; and if the equipment is used in accordance with the published instructions for use.

Should you require technical assistance, contact your Customer Service Representative.

Cytomedix, Inc.
Customer Service Response Center
209 Perry Parkway, Suite 7
Gaithersburg, MD 20877 USA

Telephone: +1 877-865-9927
Telephone: +1 301-917-6860
Fax: +1 240-499-2690
CustomerCare@Cytomedix.com
www.Cytomedix.com

Return of Used Product

If for any reason this product must be returned to Cytomedix, Inc., a returned goods authorization (RGA) number is required from Cytomedix, Inc. prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton, or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of the shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling and an RGA number may be obtained from the Cytomedix, Inc. Customer Service Response Center (877-865-9927) or CustomerCare@Cytomedix.com.

PRECAUTION

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood-borne infectious diseases.

The shipping address for returned goods is:

Cytomedix, Inc.
Customer Service Response Center
209 Perry Parkway, Suite 7
Gaithersburg, MD 20877 USA

Telephone: +1 877-865-9927
Telephone: +1 301-917-6860
Fax: +1 240-499-2690
CustomerCare@Cytomedix.com
www.Cytomedix.com

Chapter 1: Overview

Product Description

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* (*Angel® cPRP System*) consists of a blood processing device and disposable products used for separation of whole blood or mixture of blood and bone marrow into red cells, platelet poor plasma, and platelet rich plasma. The processing disposable, the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* Processing Set, is designed for single-patient use. The variable volume separation chamber allows the clinician to process from 40 ml to 180 ml of autologous whole blood or mixture of blood and bone marrow in a single cycle. A total of 180 ml can be processed over three (3) cycles per disposable.

Description of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*

How the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* Works

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* processes a determined volume of anticoagulated whole blood or mixture of blood and bone marrow from a patient and separates the blood/bone marrow into its primary components: red blood cells (RBC), platelet poor plasma (PPP), and platelet rich plasma (PRP).

The basic steps are:

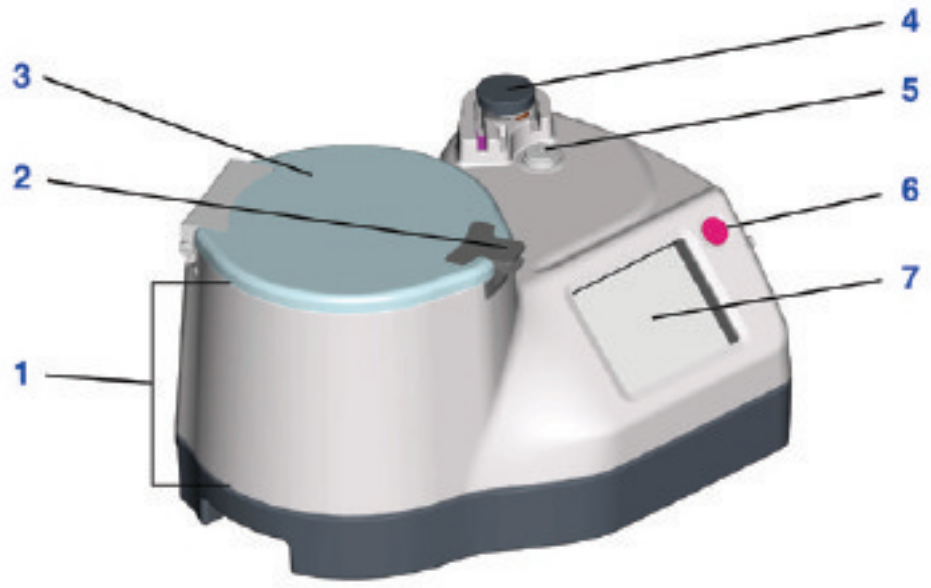
Blood Collection: The whole blood or mixture of blood and bone marrow is drawn from a patient and mixed with a citrate anticoagulant. The collected whole blood/bone marrow is mixed in a 7:1 ratio (7 parts whole blood to 1 part citrate anticoagulant (ACD-A)).

Processing: The *Angel® (cPRP) Processing Set* utilizes a variable volume separation chamber (40 ml – 180 ml) which allows the clinician to determine the amount of preoperative blood/bone marrow volume to be processed. The *Angel® cPRP Processing Set* allows for up to three processing cycles per disposable.

Once the anticoagulated whole blood or mixture of blood and bone marrow has been dispensed into the whole blood compartment of the three-compartment reservoir bag, the clinician selects the desired volume of autologous whole blood/bone marrow they elect to process and presses the “Start” button on the touch screen display. The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* will fill the variable volume disposable with the pre-determined volume of anticoagulated whole blood or mixture of blood and bone marrow, separate the whole blood/bone marrow through centrifugation, and collect the primary blood components (RBC, PPP, and PRP) in their respective collection compartments.

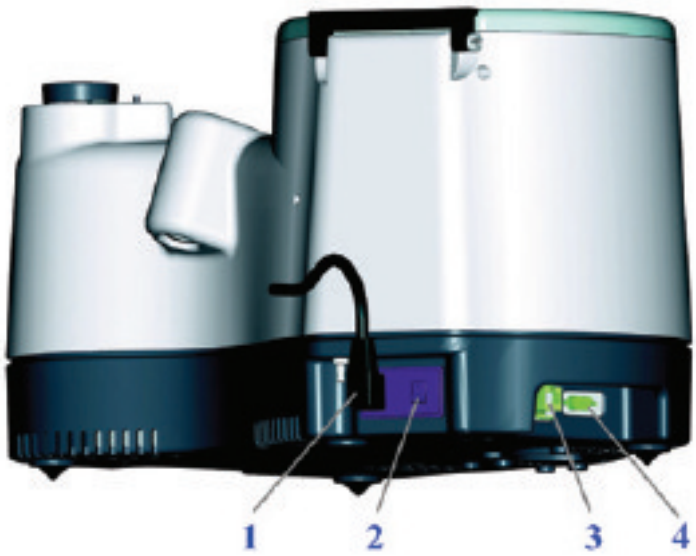
Administration: Reinfusion of blood components is under the control and supervision of the physician in charge. Follow your institution’s blood administration protocol for appropriate handling and labeling of blood components.

Angel® Concentrated Platelet Rich Plasma (cPRP) System Components



1. Centrifuge Well
2. Lid Latch Release Handle
3. Lid
4. Pump Rotor
5. Valve Assembly Driver
6. Stop Button
7. Touch Screen Display

Figure 1-1 Front-view of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*



1. Power Cord
2. Power Switch
3. Ethernet
4. USB Port

Figure 1-2 Rear-view of *Angel® Concentrated Platelet Rich Plasma (cPRP) System*

Touch Screen Display User Interface

The color touch screen provides both the controls and the necessary information for operating the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*. Below is a typical screen.

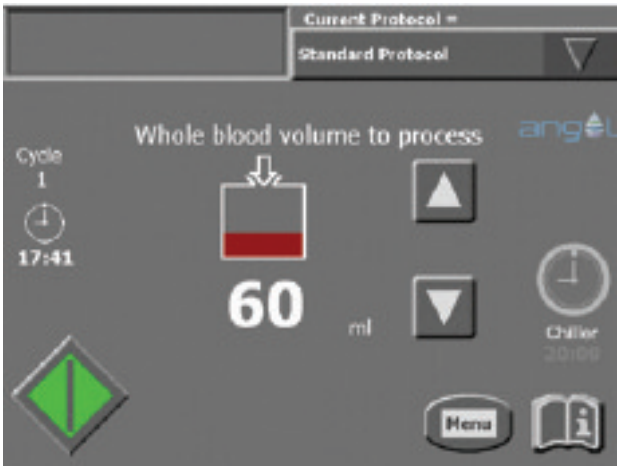


Figure 1-3 Start Screen

Shipping and Storage

1. Ship and store carton in an upright position.
2. The contents are fragile. Do not drop or jar carton.
3. Keep dry. Ship and store between 10% and 90% relative humidity.
4. Store between -20 and 37.7 degrees Celsius (-4 to 100 degrees Fahrenheit).

Installation

This section contains installation instructions for the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*. The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* has been designed to be essentially a “plug and play” device, and, as such, requires very little preparation to get started.

However, before proceeding, please note the following:

1. Read the installation procedure in its entirety.

2. Become familiar with any precautionary indications noted in this procedure.

Note: If at any time you encounter problems with the installation of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*, contact Cytomedix, Inc. Customer Service Response Center at 877-865-9927 or CustomerCare@Cytomedix.com.

Special tools, equipment and environmental requirements

There are no special tools required to install and set up this device.

PRECAUTION

Prior to first use follow the installation instructions included in this manual.

Visual Inspection

1. Inspect the exterior of the shipping container and verify that no visual damage is present.

   A. If damage is present, notify Cytomedix, Inc. Customer Service Response Center at 877-865-9927 to report the damage.

   B. If no damage is present, proceed with the installation.

Unpacking/Assembly

1. Open the shipping carton and remove the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* and all ancillary components from the shipping carton. Install the device in an operating environment between 10 and 30 degrees C (50-86 degrees F) and 10%-75% relative humidity.

2. Place the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* on a solid, flat work surface.

3. Install the power cord supplied with the equipment into the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*. Plug the power into an available power outlet

PRECAUTION

There are no user-serviceable parts inside this device. To avoid the risk of electrical shock, do not remove the cover. Refer all servicing to qualified service personnel.

Operational Checks

Power-up the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* by moving the power switch located at the back of the machine to the on position. On power-up, the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* will perform an automatic self-test. At this time, the valve assembly will also calibrate and reposition itself. Successful completion of that self-test will be evident by visual confirmation of the following start-up screen:

Current Protocol =
Standard Protocol
Please load disposable set, and lock the separation chamber plate in place.
Touch this button when the set is loaded.
Disposable set is loaded
Menu

Figure 1-4 Load Screen

No other checks or tests are required as part of this installation procedure.

Setting the Date and Time

The date and time used internally by the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* may be set from within the “Settings” tab of the Menu Screen (see Figure 1-5).

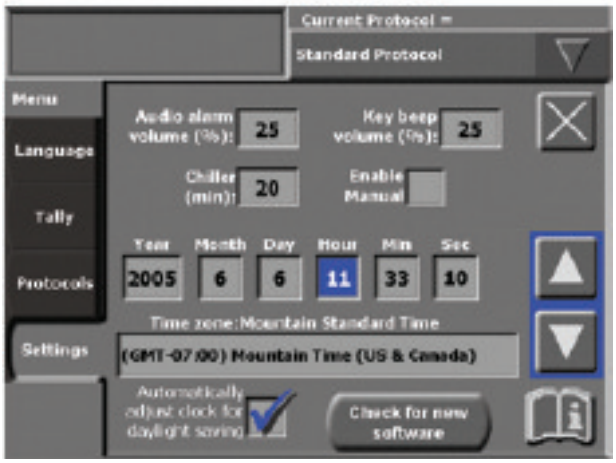


Figure 1-5 Date and Time Settings

To access the date and time settings, do the following:

1. Touch the Menu button from any screen.
2. From the Menu Screen, touch the “Settings” tab.
3. From within the “Settings” tab, touch the “Adjust date, time, or time zone” button.

The date and time settings will appear within the “Settings” tab. The settings consist of seven fields which may be adjusted: “Year”, “Month”, “Day”, “Hour”, “Min” (for minute), “Sec” (for second), and “Time zone:”

To adjust a field:

1. Touch the field you wish to adjust. For example, if you wish to change the month, click on the rectangular field labelled “Month”.

   The field will become highlighted, and the Up Arrow button and Down Arrow button will appear at the right side of the screen.

2. Touch the Up Arrow button and Down Arrow button to increase or decrease, respectively, the value of the highlighted field.

   When the “Time zone:” field is the highlighted field, touching the Up Arrow button and Down Arrow button will scroll through a list of time zones. Select your region from this list.

   When a time zone which observes Daylight Saving Time is selected, the option is given to automatically adjust the clock. This featured may be toggled on or off by touching the check-box located below the “Time zone:” field.

Setting the Date and Time (Cont.)

3. Once you are satisfied with the value of the field, you may lock in its new value in two ways: either touch the highlighted field a second time, or touch another field which needs modifying.

   When the highlighted field is touched to lock in its value, it will become not-highlighted, and the Up Arrow button and Down Arrow button will disappear.

4. Once the value of all fields have been set correctly and locked in, touch the Close button to exit the Menu Screen.

Chapter 2: Installing the Disposables

Angel® cPRP Processing Set

Description

The *Angel® cPRP Processing Set* consists of a pre-connected variable volume separation chamber, a tubing set with a platelet sensor/valve assembly, and a three-compartment reservoir bag for the collection of blood products (whole blood, red blood cells, and platelet poor plasma). The *Angel® cPRP Processing Set* also contains a 20 ml luer lock syringe for the collection of platelet rich plasma (PRP), two 60 ml specimen cups for use in a sterile field, a whole blood bag spike adapter, male-female luer plugs, and labels for collected blood components.

Major Components

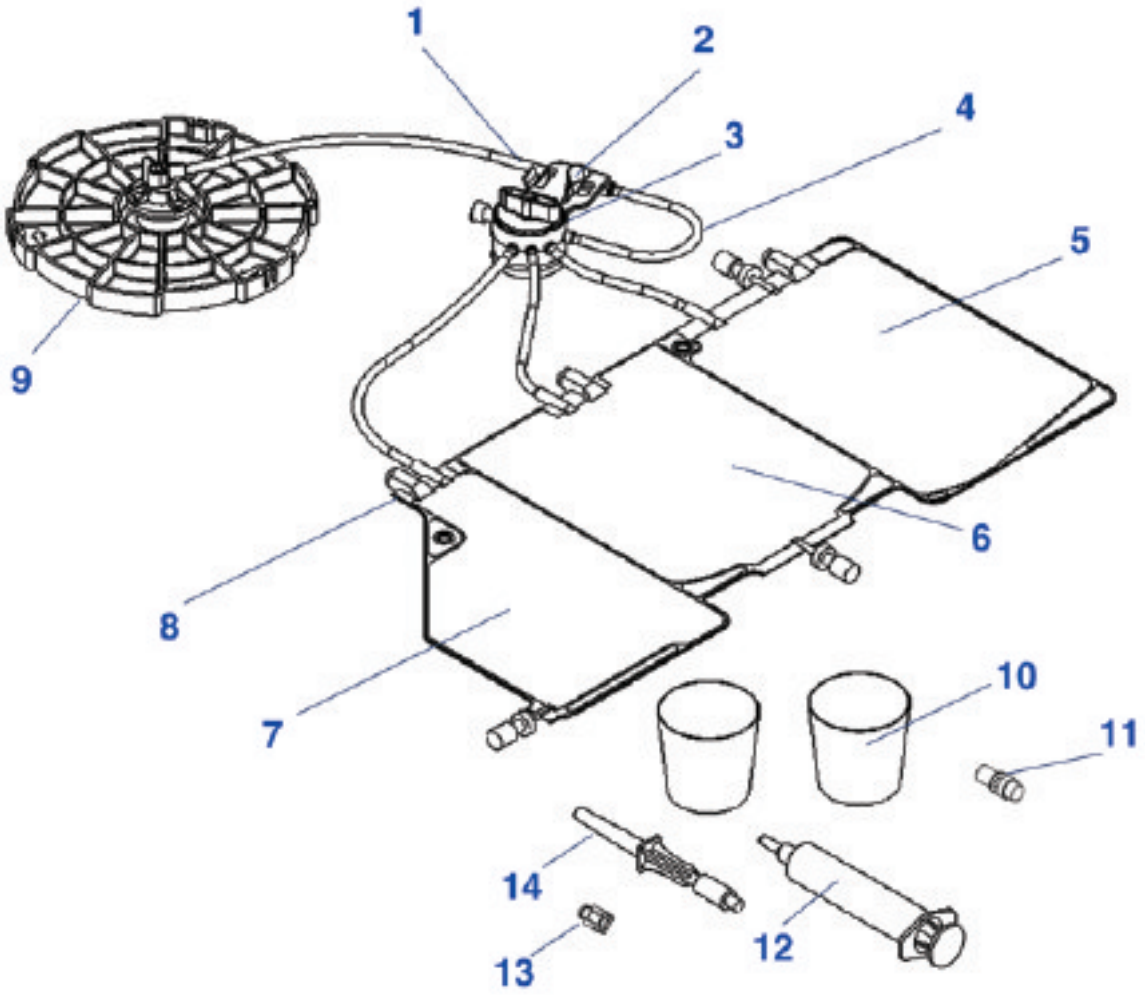
(see Figure 2-1)

Variable Volume Separation Chamber: The *Angel® cPRP Processing Set* utilizes a variable volume separation chamber that can process from 40 ml – 180 ml of anticoagulated autologous whole blood or mixture of blood and bone marrow in a single cycle. The *Angel® cPRP Processing Set* is capable of processing up to three (3) cycles per disposable.

The top half of the variable volume separation chamber (the hard plastic component) is the separation chamber plate. The separation chamber plate is used to seat the variable volume separation chamber in the centrifuge.

Platelet Cuvette/Valve Assembly: The platelet cuvette/valve assembly contains three major components: (1) the platelet cuvette, (2) the pump loop tubing and (3) the rotating valve. The platelet cuvette is seated in the platelet sensor and is used to optimize the collection of the separated blood components. The pump loop tubing is inserted around the pump, which moves volume from the whole blood compartment of the three-compartment reservoir bag to the variable volume separation chamber and from the variable volume separation chamber to the various collection compartments for the separated blood products (PRP, PPP and RBC). The rotating valve rotates throughout the course of the processing cycle to direct the whole blood, the mixture of blood and bone marrow, or its separated components through the appropriate pathway.

The platelet cuvette/valve assembly has been designed so that the operator can easily install the platelet cuvette/valve assembly while insuring that the platelet cuvette is properly seated in the platelet sensor and that the rotating valve is properly seated on the valve assembly driver.



1. Platelet Cuvette / Valve Assembly Clip
2. Platelet Cuvette
3. Rotating Valve
4. Pump Loop Tubing
5. Whole Blood Compartment
6. RBC Compartment
7. PPP Compartment
8. Three-Compartment Reservoir Bag
9. Variable Volume Separation Chamber
10. 60 ml Specimen Cups
11. Syringe-activated PRP Valve
12. 20 ml Luer Lock Syringe
13. Male-Female Luer Plug (quantity, 7 each)
14. Whole Blood Spike Adapter

Figure 2-1 ***Angel® cPRP Processing Set***

PRP Valve Port: A luer lock syringe is attached to the PRP valve port to collect PRP. At the end of a processing cycle, the PRP valve port can also be used to collect PPP. A Syringe-activated Valve is included as an accessory and can be attached to maintain a closed port when the PRP syringe is removed.

Three-Compartment Reservoir Bag: The three-compartment reservoir bag is used to collect anticoagulated whole blood, mixture of blood and bone marrow and separated blood/bone marrow components. The whole blood compartment is used as a reservoir for collected anticoagulated whole blood from a patient. The clinician may use syringes or whole blood bags to collect the anticoagulated whole blood or mixture of blood and bone marrow from a patient. The RBC Compartment is used to collect the concentrated red cells at the end of the

processing cycle. The PPP Compartment is used to collect platelet poor plasma; the PPP is the first blood component collected after separation has been completed.

Syringe-activated valves are used to access the PPP and whole blood compartments of the three-compartment reservoir bag.

Other accessory items in the *Angel® cPRP Processing Set* are:

20 ml Luer Lock Syringe: The 20 ml luer lock syringe is used for the collection of platelet rich plasma. However, the syringe-activated PRP valve will accommodate most luer fitting syringes.

60 ml Specimen Cups (2 ea.): Two 60 ml specimen cups for use in a sterile field.

Male/Female Luer Plugs: The male / female luer plugs are used during and at the end of procedure to seal open luer lock connections.

Whole Blood Bag Spike Adapter: The whole blood spike adapter is used to transfer the blood or mixture of blood and bone marrow from a whole blood bag to the whole blood compartment of the three-compartment reservoir bag.

Labels: Appropriate labels to label collected whole blood/bone marrow and separated components.

Contents of this set have been sterilized by ethylene oxide gas and have nonpyrogenic fluid pathways.

Warnings and Precautions

Please see “Warnings” on page ii in the chapter “Before You Get Started”; see “Precautions” on page iv in the same chapter.

Setup and Blood/Bone Marrow Preparation

Turning on the *Angel® cPRP System*

1. Turn on the Angel® cPRP System be pressing the power switch on the back of the machine. The message “Self test in progress. Please stand by.” will be displayed on the Angel® cPRP System’s touch screen display, and the machine will orientate the valve assembly driver to the loading position.

Figure 2-2 Rear-view of *Angel® Concentrated Platelet Rich Plasma (cPRP) System*

1. Power Switch

Initial Setup

With the *Angel® cPRP System* turned on, do the following:

Note: An instructional animation which illustrates the installation of the disposable set (described in the steps below) is available from the Info Screen immediately after powering on the *Angel® cPRP System*. (Refer to “Info Screen” on page 3-23)

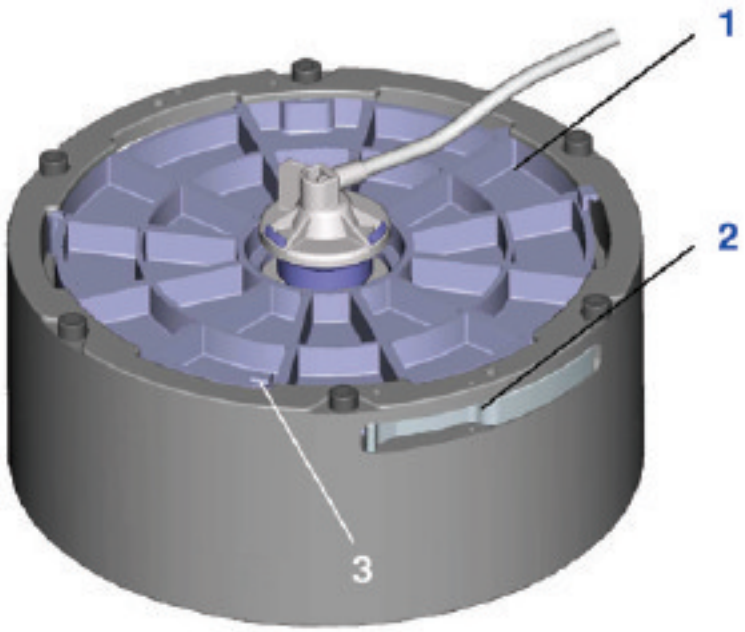
1. Open the centrifuge lid cover and lift the centrifuge stator arm to lock the centrifuge adapter within the centrifuge well.

2. Remove the *Angel® cPRP Processing Set* from the tray.

3. Lay the *Angel® cPRP Processing Set* on the top of the machine. Insert the variable volume separation chamber into the centrifuge adapter by aligning the notches in the separation chamber plate with the aligning feature on the centrifuge adapter. Once aligned, press the separation chamber plate down near the location of the position indicator and turn clockwise until the position indicator snaps into place (see Figure 2-3).

   Rotate the centrifuge to a position so that the interlock mechanism shown in Figure 2-3, item 2 does not interfere with the stator arm. If the interlock mechanism interferes with the stator arm the separation chamber plate will not load properly.

   Note: Loading the variable volume separation chamber should always be the first step in the setup process. Loading the variable volume separation chamber and pressing down on the separation chamber plate will remove excess air volume from the chamber. If excess air is not removed, the separation chamber plate will not load properly.

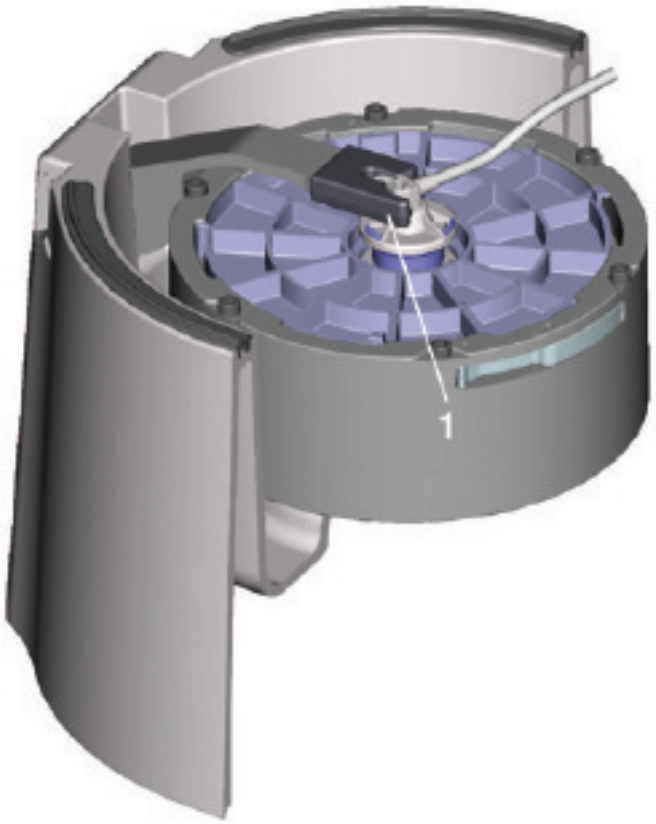


1. Separation Chamber Plate
2. Separation Chamber Plate Interlock Mechanism
3. Position Indicators

Figure 2-3 Mounting the Separation Chamber

4. Place the tube leading from the variable volume separation chamber through the slot on the rim of the centrifuge well.

5. Lower the centrifuge stator arm and align it with the mating feature on the top of the rotating seal of the variable volume separation chamber (see Figure 2-4).



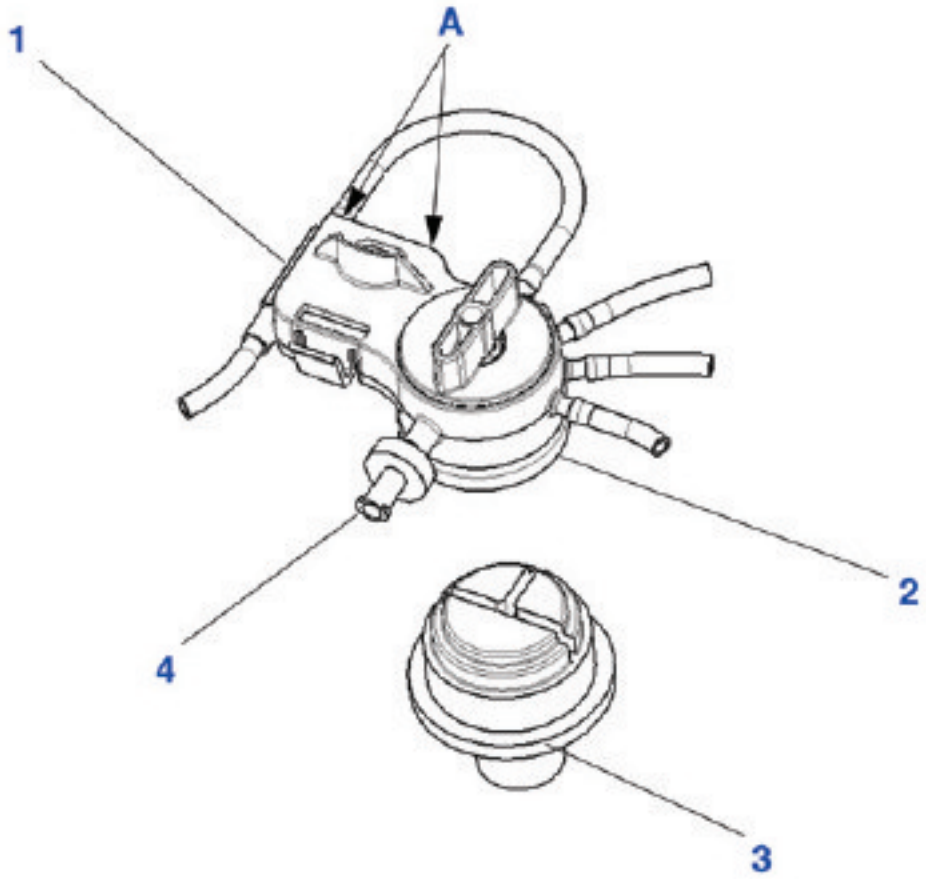
1. Stator arm lowered and aligned

Figure 2-4 Centrifuge Stator Arm Aligned with Variable Volume Separation Chamber

6. Close the centrifuge lid. After closing the centrifuge lid, make sure that the tubing remains in the slot on the rim of the centrifuge and is not occluded by the centrifuge lid.

7. Place the pump loop tubing over the pump rotor. The pump loop will automatically load when the processing cycle is initiated. Seat the platelet cuvette/valve assembly by aligning the platelet cuvette and the valve assembly with the platelet sensor body and the valve assembly driver. Press down firmly on the back side of the platelet cuvette/valve assembly, at position A near the pump loop, until the assembly is snapped in place (see Figure 2-5).

   Note: It is essential that the platelet cuvette/valve assembly seats fully on the machine to obtain proper sensing of blood components.



1. Platelet Cuvette
2. Valve Assembly
3. Valve Assembly Driver
4. Syringe-activated PRP Valve

Figure 2-5 Valve Assembly

8. Hang the three-compartment reservoir bag on the two support pins located on the side of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*.

9. Remove breather cap from the PRP valve port located on the valve assembly. If desired, attach the Syringe-activated Valve to the PRP valve port. Attach the 20 ml luer lock syringe (or alternate syringe, if desired) to the PRP valve port.

   Note: The luer on the PRP valve port will accommodate most luer-lock syringes.

10. After set-up, inspect the circuit to make sure there are no kinks or occlusions.

Blood Collection

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* utilizes a variable volume separation chamber that is capable of processing between 40 ml and 180 ml of anticoagulated whole blood or mixture of blood and bone marrow in a single cycle. A total of 180 ml can be processed over three (3) cycles per disposable.

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* can accommodate anticoagulated whole blood that has been collected preoperatively from a patient in either syringes or blood collection bags. In either situation, the patient's whole blood should be collected in a citrate anticoagulant (ACD-A) in a 7:1 ratio (seven parts whole blood to one part citrate anticoagulant (ACD-A)). The following table defines the appropriate mixture of whole blood and citrate anticoagulant (ACD-A):

Whole Blood vs. Citrate Anticoagulant Mixture

(7:1 ratio; seven parts blood to one part citrate anticoagulant)

Total Volume of Anticoagulated Whole Blood (ml)	Volume of ACD-A (ml)	Volume of Whole Blood Drawn (ml)
40[i]	5	35
50	6	44
60	8	52
70	9	61
80	10	70
90	12	78
100	13	87
110	14	96
120	15	105
130	16	114
140	18	122
150	19	131
160	20	140
170	21	149
180	23	157

[i] 40 ml anticoagulated whole blood or mixture of blood and bone marrow volumes require a patient hematocrit of 30% or greater. The recommended minimum patient hematocrit for anticoagulated whole blood volumes of 50 ml or greater is 28%.

During and after collection, gently mix the whole blood/bone marrow with the citrate anticoagulant (ACD-A) for a thorough distribution of the anticoagulant. Failure to properly mix the collected blood/bone marrow with anticoagulant may cause blood clot formation. Blood clot formation may interfere with the loading of

blood/bone marrow into the Whole Blood compartment of the three-compartment reservoir bag, and/or may interfere with the processing of the blood.

If a syringe is used to collect blood, attach the syringe to the syringe-activated valve located on the whole blood compartment of the three-compartment reservoir bag and inject the blood.

If using a whole blood collection bag to collect blood, ensure that the blood-citrate ratio is correct by weighing the bag as the blood is collected according to AABB standard methods.[1] Place the citrated (ACD-A) blood bank bag on a standard metric scale and zero it prior to beginning to withdraw the blood. Refer to the instructions for the specific bag that you are using and allow the blood to gravity drain into the bag until its weight equals the volume of the bag (1 ml of blood weighs approximately 1.053 grams).

If a mixture of blood and bone marrow is to be processed using the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System*, samples of a patient's bone marrow should be obtained using the techniques and procedures as practiced at each individual hospital or health-care setting. Equal volumes of anti-coagulated whole blood and bone marrow can be transferred into the whole blood compartment of the three-compartment reservoir bag using the syringe-activated valve or Whole Blood Bag Spike Adapter.

Use the Whole Blood Bag Spike Adapter to transfer the blood or mixture of blood and bone marrow to the whole blood compartment of the three-compartment reservoir bag. Luer lock the Whole Blood Bag Spike Adapter to the syringe-activated valve located on the whole blood compartment of the three-compartment reservoir bag and spike the blood collection bag to drain the blood or mixture of blood and bone marrow into the whole blood compartment. After the blood/bone marrow has drained into the whole blood compartment of the three-compartment reservoir bag, remove the Whole Blood Bag Spike Adapter and recap the syringe-activated valve.

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[1]Method 9.3. Phelbotomy and Collection. Technical Manual. American Association of Blood Banks. AABB Press. Bethesda, MD.1996.

Chapter 3: Processing

Before You Begin

Loading the *Angel® cPRP System*

The proceeding information assumes you have followed the instructions in Chapter 2: Installing the Disposables, beginning with “Turning on the *Angel® cPRP System*” on page 2-3.

The Load Screen will be displayed on the *Angel® cPRP System’s* touch screen display (see Figure 3-1).

Current Protocol =
Standard Protocol
Please load disposable set, and lock the separation chamber plate in place.
Touch this button when the set is loaded.
Disposable set is loaded
Menu

Figure 3-1 Load Screen

1. If the disposables are loaded according to the instructions in Chapter 2, touch the “Disposable set is loaded” button.

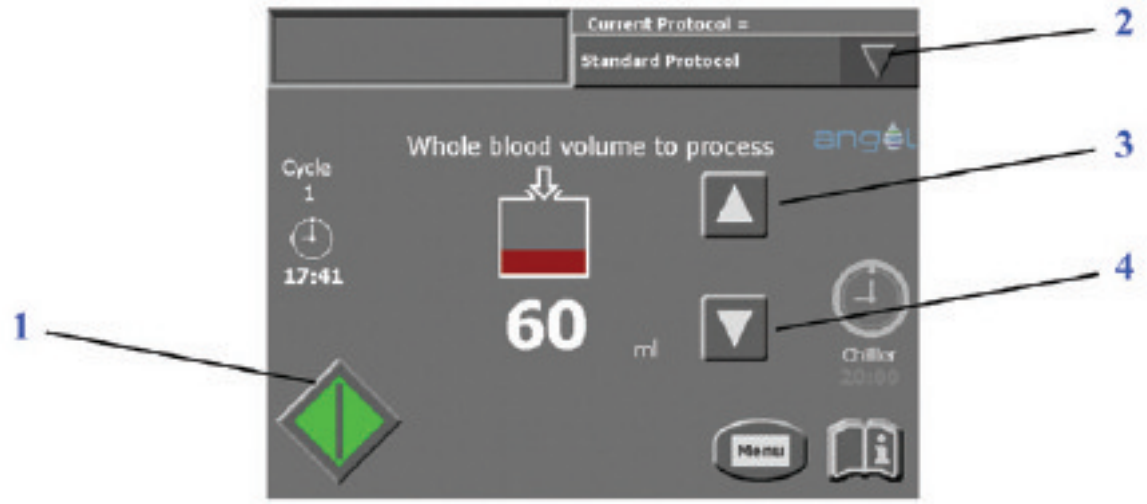
Collecting the Blood or Mixture of Blood and Bone Marrow

Collect the blood or mixture of blood and bone marrow according to “Blood or Mixture of Blood and Bone Marrow Collection” on page 2-8.

Running the Separation Process

Once the *Angel® cPRP Processing Set* is loaded and the “Disposable set is loaded” button has been touched, the Start Screen should be displayed (see Figure 3-2). The system is now ready.

1. From the Start Screen (see Figure 3-2), select the desired protocol using the Protocol pull-down button (unless the displayed protocol is already what you want).



1. Start Button
2. Protocol Pull-Down Button
3. Up Arrow Button
4. Down Arrow Button

Figure 3-2 Start Screen

For a detailed explanation of the Start Screen, read “Start Screen” on page 3-11.

2. Select the whole blood or mixture of blood and bone marrow volume to process using the Up Arrow button and Down Arrow button. If the volume of anticoagulated whole blood or mixture of blood and bone marrow available is less than the selected volume to be processed, the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* will process the available volume. The minimum processing volume required is 40 ml of whole blood/bone marrow.

3. Touch the Start button to begin processing.

   The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* will draw the selected volume of anticoagulated whole blood or mixture of blood and bone marrow from the whole blood compartment of the three-compartment reservoir bag into the variable volume separation chamber, where it will undergo separation.

   This process is monitored by the Run Screen (see Figure 3-3).

   Note: If, after starting the cycle, you need to change the selected volume of whole blood or mixture of blood and bone marrow to process, you may do so by touching the Modify Volume button from the Run Screen, illustrated below and described on page 3-15.

   Note: If the Insufficient fill alarm is triggered, see the response in “Alarms and Notifications” on page 5-1.

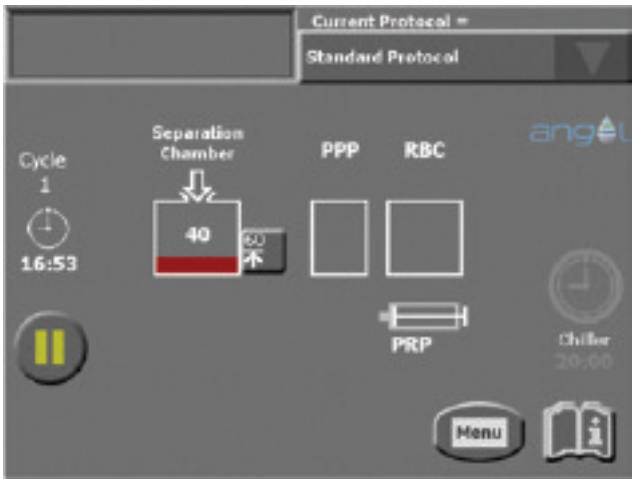


Figure 3-3 Run Screen

For a detailed explanation of the Run Screen, read “Run Screen” on page 3-13.

During the collection of the blood components, the volumes displayed and the process time displayed may be adjusted by the machine software to reflect more accurate values.

Once separation is complete, and all components are collected, the End of Cycle Screen is displayed on the *Angel® cPRP System’s* touch screen display (see Figure 3-4).

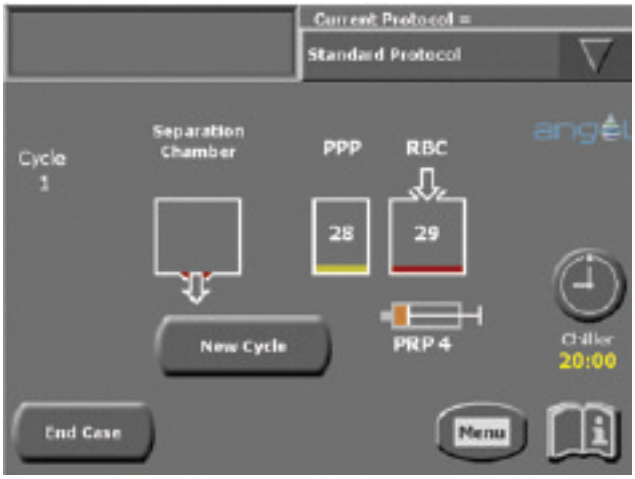


Figure 3-4 End of Cycle Screen

For a detailed explanation of the End of Cycle Screen, read “End of Cycle Screen” on page 3-15.

Note: If, for any reason, you need to stop a cycle before the separation process is complete, please refer to “Stop Button” on page 3-24.

If desired, after each processing cycle, the PRP may be diluted to increase total volume by drawing back the PRP syringe plunger. This will draw PPP from the PPP Compartment of the three-compartment reservoir bag into the PRP syringe.

At the end of the case, the RBC Compartment of the three-compartment reservoir bag will contain concentrated red blood cells, while the PPP Compartment of the three-compartment reservoir bag will contain platelet poor plasma.

Note: Prior to processing more than one cycle of blood or mixture of blood and bone marrow, agitate the Whole Blood Compartment of the reservoir bag. Agitation of the Whole Blood Compartment will mix the remaining blood, providing a more uniform collection of blood components.

4. The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* allows a maximum total processing volume of 180 ml. If the maximum volume has not been reached and the available volume is greater than 40 ml, the “New Cycle” button will be available. Touching the “New Cycle” button will display the Start Screen (see Step 2). Otherwise, end the case by touching the “End Case” button. Touching the “End Case” button will display the End of Case Screen, which displays the total amounts of RBC, PPP, and PRP collected during the case (see Figure 3-5).

   The End of Case Screen allows for saving case data (refer to “Saving Case Data” on page 3-5). The End of Case Screen also allows the entering of case data (refer to “Entering Optional Case Data Fields” on page 3-6).

Figure 3-5 End of Case Screen

For a detailed explanation of the End of Case Screen, read “End of Case Screen” on page 3-15.

5. Remove and properly dispose of the *Angel® cPRP Processing Set* in the following way:

   a. Open the centrifuge lid cover and lift the stator arm to lock the centrifuge adapter within the centrifuge well. Remove the variable volume separation chamber by twisting it counter-clockwise and then lifting it out of the centrifuge adaptor.

      Rotate the centrifuge to a position so that the interlock mechanism shown in Figure 2-3, item 2 does not interfere with the stator arm. If the stator arm interferes with the interlock mechanism the separation chamber plate will not unload properly.

Note: Use the Male-Female Luer lock plugs provided to close all open ports before removing the processing set from the machine.

   b. Remove the platelet cuvette / valve assembly by grasping the platelet cuvette / valve assembly release tab and lifting upwards. To remove the pump loop tubing from the pump rotor, turn the pump rotor and pull the pump loop tubing from it.

   c. Remove the three-compartment reservoir bag from the support pins on the side of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*.

6. Turn off the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* using the switch at the rear of the machine.

Saving Case Data

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* stores a tally table and a detailed log file about every case that has been processed, with the option to save the tally table as an easy to read, printable text file and to save the detailed case log file.

Tally tables and case logs may be saved to USB storage devices. Case logs may be saved to a USB storage device or network server.

Note: When using the USB or Ethernet Network connections, it is recommended that the appropriate Data Integrity Accessory is used. (Refer to Section 6.)

Every case includes the following information which is available as an easily viewable and printable text file:

- The case number, a sequential number assigned by the machine to every case; the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* serial number; the date and time at which the case was started; and the *Angel® cPRP System* software version number.
- The “ID” field as entered by the operator (refer to “Entering Optional Case Data Fields” on page 3-6).
- The “Operator” field as entered by the operator (refer to “Entering Optional Case Data Fields” on page 3-6).
- The tally table: the volumes (ml) of the whole blood or mixture of blood or bone marrow volume processed by the case, as well as volumes of RBC, PPP, and PRP collected during each cycle of the case. When available, the start and end times of the case, as well as the protocol used during processing, appear with the tally table.
- The “Notes” field as entered by the operator (refer to “Entering Optional Case Data Fields” on page 3-6).

The optional fields may be left blank, represented in the output by blank lines.

There are two places within the Touch Screen user interface from which case data may be saved once processing of the case has completed:

- The End of Case Screen, which appears upon completion of processing for every case (see Figure 3-5)
- The “Tally” tab of the Menu Screen (see Figure 3-6)

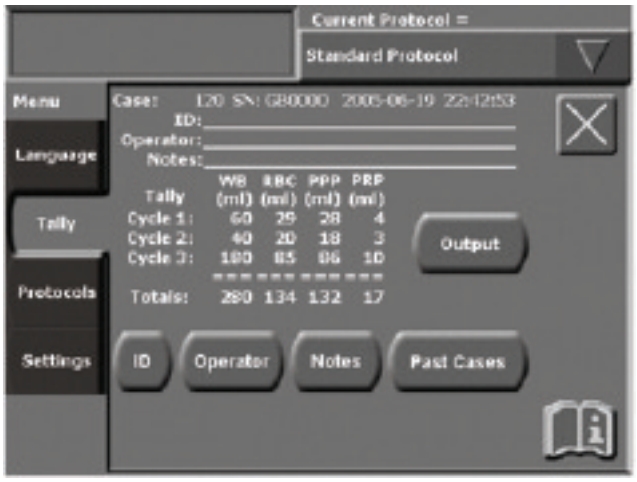


Figure 3-6 “Tally” tab of the Menu Screen

For a detailed explanation of the “Tally” tab, read “Tally Tab” on page 3-18.

The “Tally” tab of the Menu Screen may be accessed at any time during a case by touching the Menu button, and then touching the “Tally” tab.

All of the instructions in this section may be performed from either the End of Case Screen or the “Tally” tab of the Menu Screen.

Entering Optional Case Data Fields

In addition to the standard data stored for each case, such as the volumes of collected RBC, PPP, and PRP, the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* provides three optional data fields which may be entered by the operator in order to be saved with the standard case data:

- “ID” field: an identification tag for the case chosen by the operator, may contain letters, numbers, or symbols.
- “Operator” field: the name of the person operating the *Angel® cPRP System* during the case.
- “Notes” field: any notes the operator wishes to store along with a case.

Values for the “ID”, “Operator”, and “Notes” fields may only be entered for the current case. The data of past cases cannot be modified.

To enter or modify the values of the data fields from either screen, perform the following steps:

1. Touch the button at the bottom of the screen (see Figure 3-6) which corresponds with the field you wish to enter. For example, touch the “ID” button to enter a value for the “ID” field (see Figure 3-6). The Keyboard Screen will be displayed on the Touch Screen user interface (see Figure 3-7).

Current Protocol =
Low Crit
Type in text, then touch Enter to save
PN137
Backspace
1 2 3 4 5 6 7 8 9 0
Q W E R T Y U I O P
A S D F G H J K L ;
Alt Z X C V B N M , .
Caps & Numbers
Space
Clear
Enter

Figure 3-7 Keyboard Screen (Text Entry)

2. Using the Keyboard Screen, type the desired value for the field.

3. Once you are satisfied with the value you have entered, touch the “Enter” button, located at the lower right corner of the Keyboard Screen.

   The value of the field will be saved and you will return to the “Tally” tab or End of Case Screen.

   You may exit the Keyboard Screen without causing any changes to be saved by touching the Close button located at the upper right corner of the screen.

4. Repeat the previous steps for all three fields, if desired.

Modifying Optional Data Field Values

The following applies to a current case only. After entering values for the optional data fields (as described in “Entering Optional Case Data Fields” on page 3-6), you may modify them before beginning a new case. Once a new case is begun, the values entered for the “ID”, “Operator”, and “Notes” fields may no longer be modified.

To modify a previously entered value for a field on the current case, perform the following steps:

1. Touch the button at the bottom of the screen which corresponds with the field you wish to enter (for example, touch the “ID” button to enter a value for the “ID” field). The Keyboard Screen will be displayed on the touch screen display (see Figure 3-7).

   The original value of the field will be entered into the text field at the top of the Keyboard Screen.

2. Modify or make corrections to the field. You may use the “Backspace” button, located at the top of the Keyboard Screen, to delete characters from the field one at a time, or the “Clear” button, located at the bottom of the Keyboard Screen, to delete all characters at once.

3. Once you are satisfied with the field's new value, touch the "Enter" button, located at the lower left corner of the Keyboard Screen.

   The value of the field will be saved and you will return to the "Tally" tab or End of Case Screen.

   You may exit the Keyboard Screen without saving any changes by touching the Close button located at the upper right corner of the screen.

4. Repeat the previous steps for all fields which require modification.

Selecting Past Cases

By default, both the End of Case Screen and the "Tally" tab of the Menu Screen only display and allow for the saving of the current case. To select past cases for display or saving, perform the following steps:

1. Touch the "Past Cases" button (see Figure 3-8).

   The Past Cases Screen will appear on the *Angel® cPRP System's* touch screen display (see Figure 3-8).

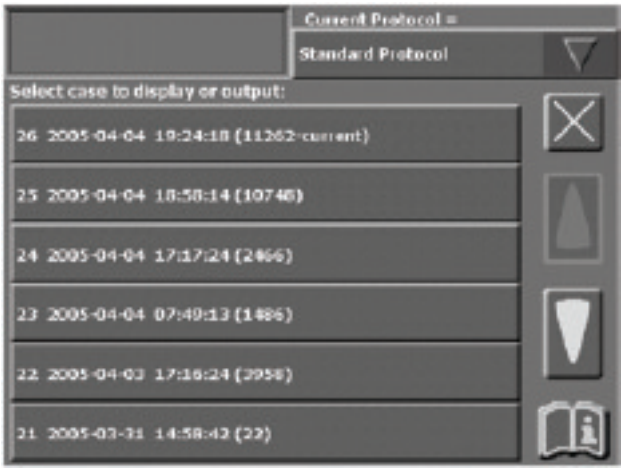


Figure 3-8 Past Cases Screen

For a detailed explanation of the Past Cases Screen, read "Past Cases Screen" on page 3-21.

2. From the Past Cases Screen, locate and touch the case you wish to view or save. Navigate through the list of past cases by touching the arrow buttons on the right side of the screen.

   You will be returned to the End of Case Screen or the "Tally" tab of the Menu Screen, where you may save the selected case.

   You may exit the Past Cases Screen without selecting a case by touching the Close button located at the upper right corner of the screen.

   To return to the current case after viewing or saving a past case, return to the Past Cases Screen and select the case at the very top of the list marked "(current)".

Saving a Tally Table to a USB Storage Device

Perform the following steps to save the tally table of a case:

1. Ensure that a USB storage device is connected to the USB port of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*.

2. If you do not wish to save the tally table of the current case, then follow the procedure in “Selecting Past Cases” on page 3-8 to select a past case.

3. Touch the “Output” button.

   The Output Screen will appear on the *Angel® cPRP System’s* touch screen display (see Figure 3-9).

   The *Angel® cPRP System* will then scan for a connected storage device. While it does this, the text “Searching for connected devices. Please wait…” will appear on the Output Screen.

   If a USB storage device is detected, then the “Output Tally to USB storage device” button will become enabled.

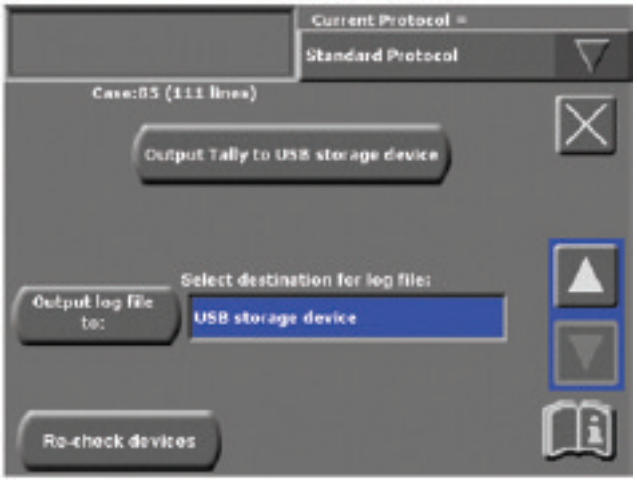


Figure 3-9 Output Screen

For a detailed explanation of the Output Screen, read “Output Screen” on page 3-22.

4. Touch the “Output Tally to USB storage device” button.

A progress bar may briefly appear to monitor the progress of the saving process. Once the entire tally table has been saved, the text “Output saved” will be displayed beneath the “Output Tally to USB storage device” button and you will be returned to the Output Screen.

The Tally Table can be retrieved from the USB storage device via a PC for later viewing or printing. Each Tally Table is saved in a single text file named with the format “<Serial Number>-<Case Number>.txt”. So, for example, if the serial number of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* on which the case is run is “GB0000” and the case number of the saved tally table is “00030”, then the name of the file which contains the tally table when saved to a USB storage device would be “GB0000-00030.txt”.

If the “Output Tally to USB storage device” button never becomes enabled, or if the message “Output failed!” appears when trying to save the tally table, consult “Troubleshooting the Save Process” on page 5-8.

You may exit the Output Screen without causing any changes to take effect by touching the Close button located at the upper right corner of the screen.

Saving a Case Log

The data for the present or any past case may be saved to an external USB storage device.

1. Ensure that a supported USB storage device is connected to the USB port.

2. If you do not wish to save the current case, then select a past case to save as described in “Selecting Past Cases” on page 3-8.

3. Touch the “Output” button.

   The Output Screen will appear on the *Angel® cPRP System’s* touch screen display (see Figure 3-9).

   The *Angel® cPRP System* will then scan for a connected storage device. While it does this, the text “Searching for connected devices. Please wait…” will appear on the Output Screen.

   If a USB storage device is detected, then the “Output log file to:” button will become enabled.

4. If multiple destinations are available (such as both a USB storage device and a network server), choose the appropriate destination by performing the following:

   a. Touch the “Select destination for log file:” field.

      The field will become highlighted, and the Up Arrow button and Down Arrow button will appear at the right side of the screen.

   b. Touch the Up Arrow button and Down Arrow button to scroll through available destinations which the log may be saved to.

5. Once you have chosen your desired destination, touch the “Output log file to:” button.

A progress bar will appear to monitor the progress of the saving process. Once all data lines have been saved, the text “Output saved” will be displayed beneath the “Output log file to:” button and you will be returned to the Output Screen.

If the Stop button is pressed while the case is being saved, the save process will stop, and an “Output Failed!” message will display.

If the “Output Tally to USB storage device” button or the “Output log file to:” button never become enabled, or if the message “Output failed!” appears when trying to save, consult “Troubleshooting the Save Process” on page 5-8.

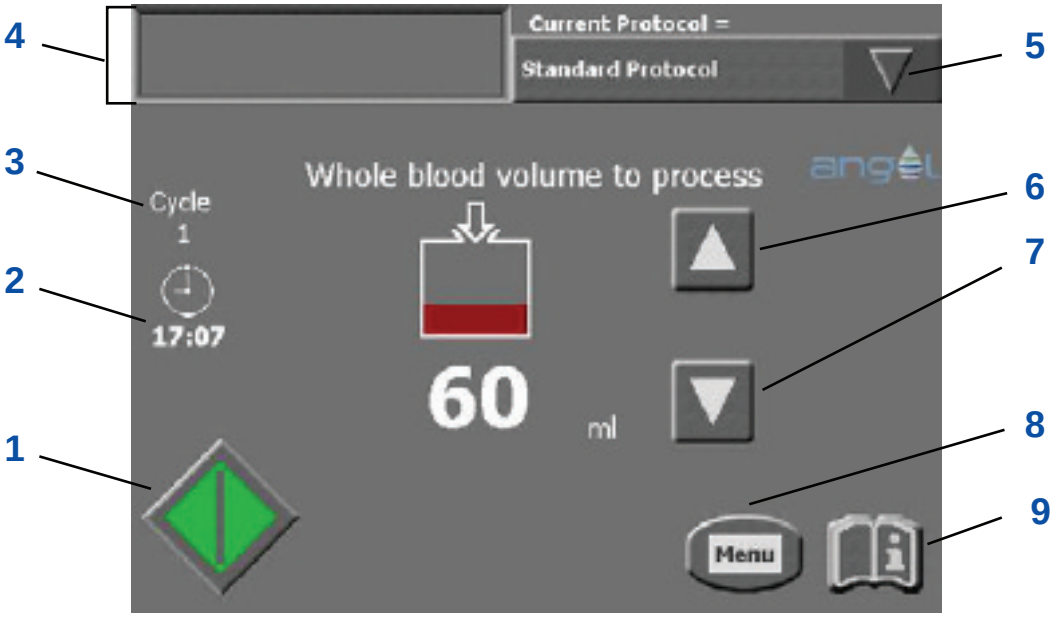
At any time, you may exit the Output Screen without causing any changes to take effect by touching the Close button located at the upper right corner of the screen. When you close this screen, you will be returned to the End of Case Screen or the “Tally” tab.

Touch Screen User Interface

The following section offers a detailed description of the user interface, focusing on the screens encountered during normal use.

Start Screen

Once the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* has completely loaded, the Start Screen is displayed on the *Angel' cPRP System's* touch screen display. The Start Screen is used to select the whole blood or mixture of blood and bone marrow volume to process and to begin each processing cycle (see Figure 3-10).



1. Start button
2. Processing Time
3. Cycle Enumerator
4. Alarm Area
5. Protocol pull-down button
6. Up Arrow button
7. Down Arrow button
8. Menu button
9. Info button

Figure 3-10 Start Screen

1. Start Button

The Start button will begin the blood separation processing cycle. Before touching the Start button, set the desired volume of whole blood or mixture of blood and bone marrow to process using the Up Arrow button and Down Arrow button.

2. Processing Time

The "mm:ss" formatted time displayed underneath the analog clock icon indicates the amount of processing time required before PRP will be collected once the processing cycle begins. The time is based on the amount of whole blood or mixture of blood and bone marrow volume selected for processing (using the Up Arrow button and Down Arrow button). As the Up Arrow button and Down Arrow button are touched, the processing time will interactively change to reflect the newly selected volumes.

In all screens other than the Start Screen, the processing time displays and counts down the amount of time remaining in the current cycle before PRP is collected.

3. Cycle Enumerator

The cycle enumerator displays the current cycle number in any screen. Each case may run up to three cycles. After each cycle, the operator must check the PRP volume collected to ensure that the PRP syringe does not overfill.

4. Alarm Area

Alarms are shown as icons in the alarm area. Touching the icon will bring up a context-sensitive information screen that describes the alarm in detail. The various icons which may appear in the alarm area are detailed in “Alarms and Notifications” on page 5-1.

5. Protocol Pull-Down Button

The name of the currently loaded protocol is displayed to the left of the Protocol pull-down button. Touching the Protocol pull-down button will display a list of available protocols; touching the Protocol pull-down button a second time collapses the list. Touching a protocol’s name in the list will select it as the protocol to be used during processing. The protocol may be changed after each cycle of a case.

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* ships with a single Standard Protocol. The Standard Protocol is locked in the computer’s memory and cannot be altered or deleted.

Refer to Chapter 4: Programmability Option for additional information on protocols and creating custom protocols.

6-7. Up and Down Arrow Buttons

Touching the Up Arrow button and Down Arrow button will increase and decrease, respectively, the whole blood or mixture of blood and bone marrow volume to process. The volume set to be processed is displayed by the number (in ml) in the center of the touch screen display, and is reflected by the icon labeled “whole blood volume to process”.

A total of 180 ml can be processed over three (3) cycles per disposable. A cycle can process from 40 to 180 ml of blood or mixture of blood and bone marrow. The default volume is 60 ml.

8. Menu Button

Touching the Menu button will bring up the Menu Screen. Various *Angel® cPRP System* settings can be adjusted from the Menu Screen. Touching the Close button in the Menu Screen will close the Menu Screen and display the previously displayed screen. Refer to the section “Menu Screen” on page 3-17.

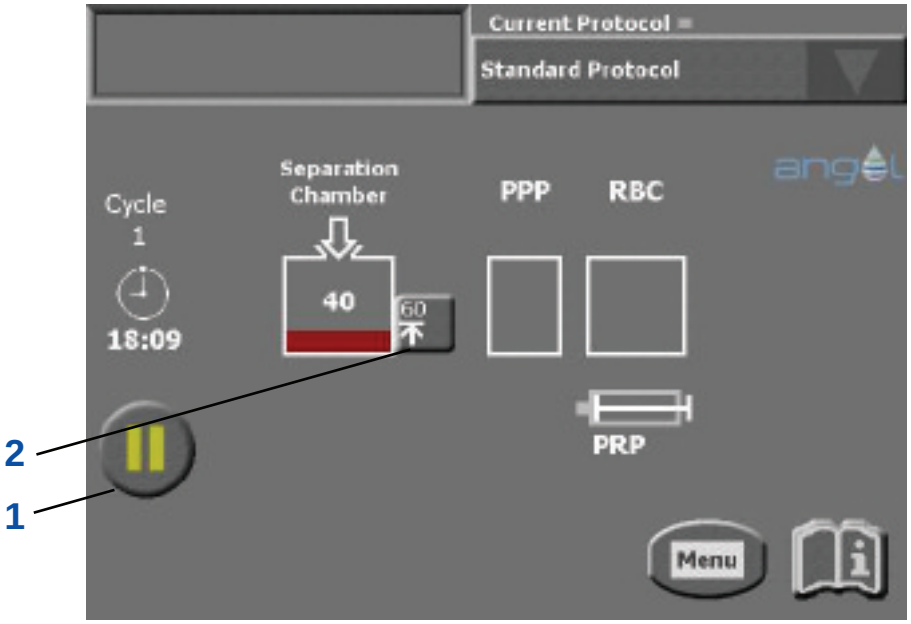
9. Info Button

Touching the Info button from any screen may bring up an Info Screen containing contextual help for that screen. Touching the Close button from the Info Screen will return you to the previously displayed screen. Refer to the section “Info Screen” on page 3-20.

Run Screen

The Run Screen tracks the progress of the blood separation process by dynamically displaying (in ml) the amount of RBC, PPP, and PRP collected throughout the processing cycle (see Figure 3-11).

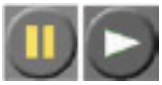
A tally of the total whole blood/bone marrow processed and the RBC, PPP, and PRP collected during a case may be viewed at any time by touching the Menu button, and then touching the “Tally” tab from the Menu Screen (see Figure 3-15).



1. Pause/Resume Button 2. Modify Volume Button

Figure 3-13 Run Screen

Pause/Resume Button



Processing may be paused at any time from the Run Screen by touching the Pause/Resume button (the yellow bars). When the system is paused, the word “Paused” appears below the processing time.

A paused processing cycle may be resumed by touching the Pause/Resume button a second time (the green arrow).

Modify Volume Button

The volume of whole blood or mixture of blood and bone marrow which has been selected to process is displayed within the Modify Volume button (ml). Touching the Modify Volume button allows the operator to change this volume during the fill stage of processing.

Touching the Modify Volume button pauses the system and displays a screen similar to the Start Screen where the operator may use the Up Arrow button and Down Arrow button to increase or decrease, respectively, the volume of whole blood or mixture of blood and bone marrow to process (refer to “Start Screen” on page 3-11). A volume less than that already within the variable volume separation chamber cannot be selected.

Once the new volume has been selected, touching the green Resume button will continue the processing cycle.

The Modify Volume button is only available during the fill stage of processing, before the originally selected volume of whole blood to be processed has been pumped into the variable volume separation chamber.

Variable Volume Separation Chamber

The icon labeled “Separation Chamber” represents the state (filling, spinning, or emptying) of the variable volume separation chamber. The number displayed inside the icon is the approximate volume (ml) of blood currently in the variable volume separation chamber.

PPP

The icon labeled “PPP” represents the state of the PPP Compartment of the three-compartment reservoir bag. The number displayed is the approximate volume (ml) of PPP collected. (The number is *not* displayed until the first volume of PPP is collected.)

RBC

The icon labeled “RBC” represents the state of the RBC Compartment of the three-compartment reservoir bag. The number displayed is the approximate volume (ml) of RBC collected. (The number is *not* displayed until the first volume of RBC is collected.)

PRP

The icon labeled “PRP” represents the state of the PRP syringe. The number displayed is the approximate volume (ml) of PRP collected by the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*. (The number is *not* displayed until the first volume of PRP is collected.)

End of Cycle Screen

The End of Cycle Screen appears at the end of each processing cycle and displays the total volumes collected of the three separated blood components: PPP, PRP, and RBC (see Figure 3-12).

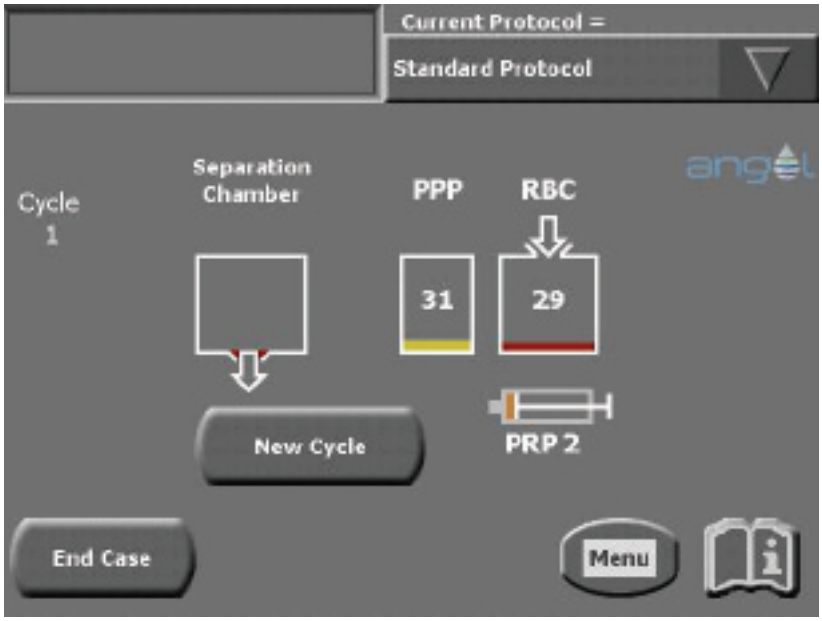


Figure 3-12 End of Cycle Screen

"New Cycle" Button

If the maximum volume has not been reached and the available volume is greater than 40 ml, the "New Cycle" button will be available. Touching the "New Cycle" button begins a new cycle and displays the Start Screen (see "Start Screen" on page 3-11). During and after each cycle, the operator must pay attention to the PRP volume collected so that the syringe does not overfill (after touching the "New Cycle" button, the text "Check PRP syringe!" will appear beneath the alarm area as a reminder).

"End Case" Button

Touching the "End Case" button ends the current case and displays the End of Case Screen (see "End of Case Screen" on page 3-15).

End of Case Screen

The End of Case Screen appears at the end of each case and displays information about the case (see Figure 3-13). From the End of Case Screen, the operator may save case data to an external USB storage device.

See *"Running the Separation Process"* on page 3-1 for instructions on unloading the *Angel® cPRP Processing Set*.

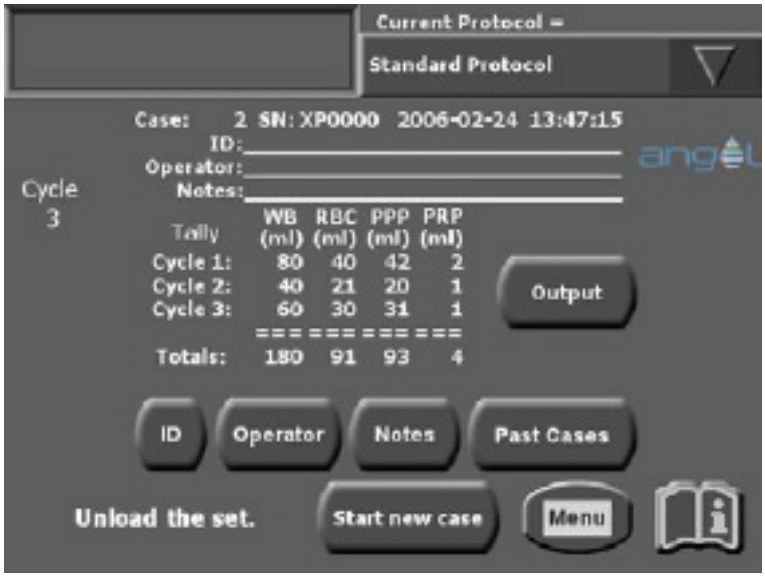


Figure 3-13 End of Case Screen

The topmost line of the End of Case Screen consists of the following information, from left to right: a sequential case number assigned by the machine to each case, the serial number of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*, and the date and time at which the case was started.

The next lines are three fields: “ID”, “Operator”, and “Notes”. All three fields will be blank until their values are assigned using the “ID” button, “Operator” button, and “Notes” button located towards the bottom of the screen. To learn how to enter values for these fields, which will appear in saved tally tables, refer to the section “Entering Optional Case Data Fields” on page 3-6.

The tally table in the center of the End of Case Screen displays the total volume of whole blood or mixture of blood and bone marrow processed in the first column, followed by the total volumes of RBC, PPP, and PRP collected in each cycle. The totals at the bottom of each column reflect the volumes of the entire case.

The six buttons near the tally table are used for entering case information, and for displaying and saving cases. To learn how to do this, refer to the section “Saving Case Data” on page 3-5. The buttons’ functions are described below.

“Past Cases” Button

Touching the “Past Cases” button will bring up the Past Cases Screen. From the Past Cases Screen, past cases may be selected for viewing or saving. To learn how to select past cases for viewing or saving, refer to “Selecting Past Cases” on page 3-8. For a detailed explanation of the Past Cases Screen, read “Past Cases Screen” on page 3-21.

“Output” Button

Touching the “Output” button will bring up the Output Screen. From the Output Screen, case data may be saved to an external storage device. To learn how to save case data, refer to “Saving Case Data” on page 3-5. For a detailed explanation of the Output Screen, read “Output Screen” on page 3-22.

"ID" Button

The "ID" button is used to enter or modify the value of the "ID" field, which is saved along with the rest of the case data. To learn how to enter the values of a case's optional fields, refer to "Entering Optional Case Data Fields" on page 3-6.

"Operator" Button

The "Operator" button is used to enter or modify the value of the "Operator" field, which is saved along with the rest of the case data. To learn how to enter the values of a case's optional fields, refer to "Entering Optional Case Data Fields" on page 3-6.

"Notes" Button

The "Notes" button is used to enter or modify the value of the "Notes" field, which is saved along with the rest of the case data. To learn how to enter the values of a case's optional fields, refer to "Entering Optional Case Data Fields" on page 3-6.

"Start new case" Button

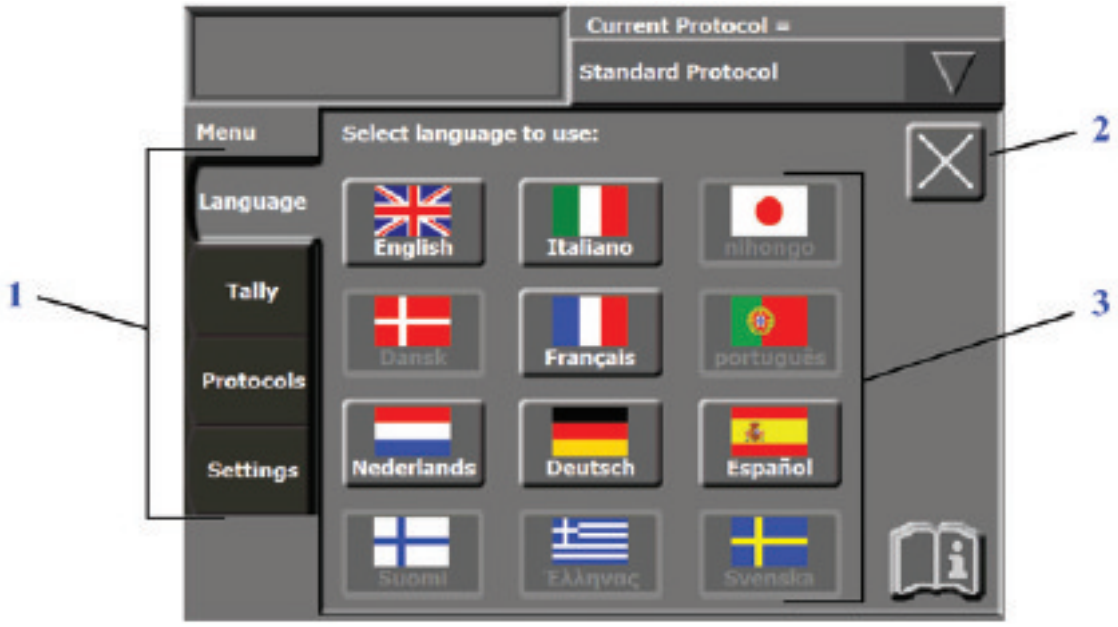
The "Start new case" button is used to begin a new processing case. If another case is not to be run at the present time, shut down the machine per the steps in "Running the Separation Process" on page 3-1.

Menu Screen

Touching the Menu button from any screen displays the Menu Screen which consists of a list of tabs. Touching one of the tabs will display the associated menu screen.

Language Tab

The "Language" tab is used to select the language which the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System* will use when displaying text (see Figure 3-14).



1. Tabs 2. Close Button 3. Language Buttons

Figure 3-14 "Language" tab of the Menu Screen

1. **Tabs**
   Touching a Tab will display the Menu Screen associated with it.

2. **Close Button**
   Touching the Close button will close the Menu Screen and return you to the previously displayed screen.

3. **Language Buttons**
   Touching one of the Language buttons will cause the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* to display all text in that language.

Tally Tab

The “Tally” tab of the Menu Screen displays information about the case which just completed processing and allows the operator to save that information (see Figure 3-15).

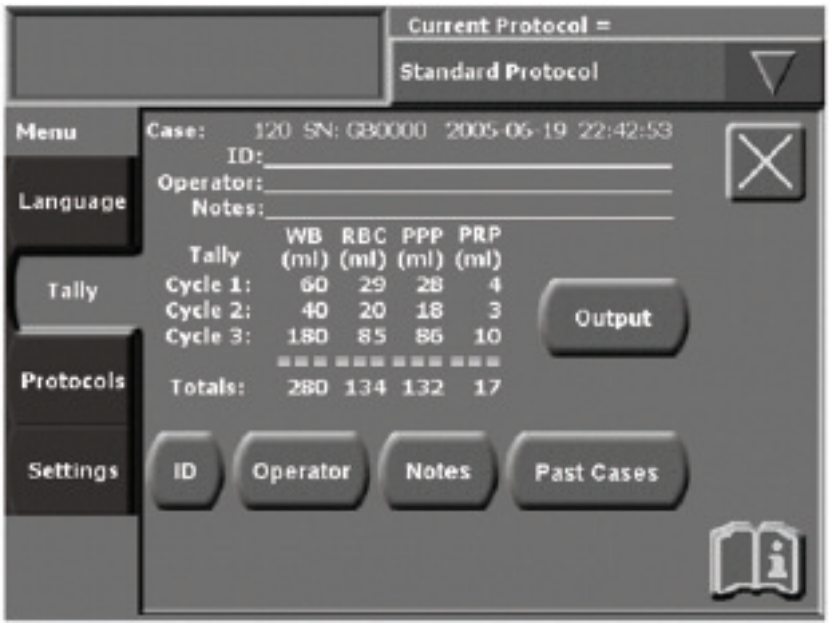


Figure 3-15 Tally Tab of the Menu Screen

The information and all interface buttons present in the “Tally” tab of the Menu Screen are identical to those contained in the End of Case Screen. For a detailed description, read “End of Case Screen” on page 3-15.

For instructions on how to save case data from the “Tally” tab, refer to “Saving Case Data” on page 3-5.

Protocols Tab

The “Protocols” tab allows for the creation and management of custom protocols. See Chapter 4: Programmability Option.

Settings Tab

The “Settings” tab is used to change the volume of audible alarms, set the date and time used internally by the *Angel® cPRP System*, and to check for new software versions (see Figure 3-16).

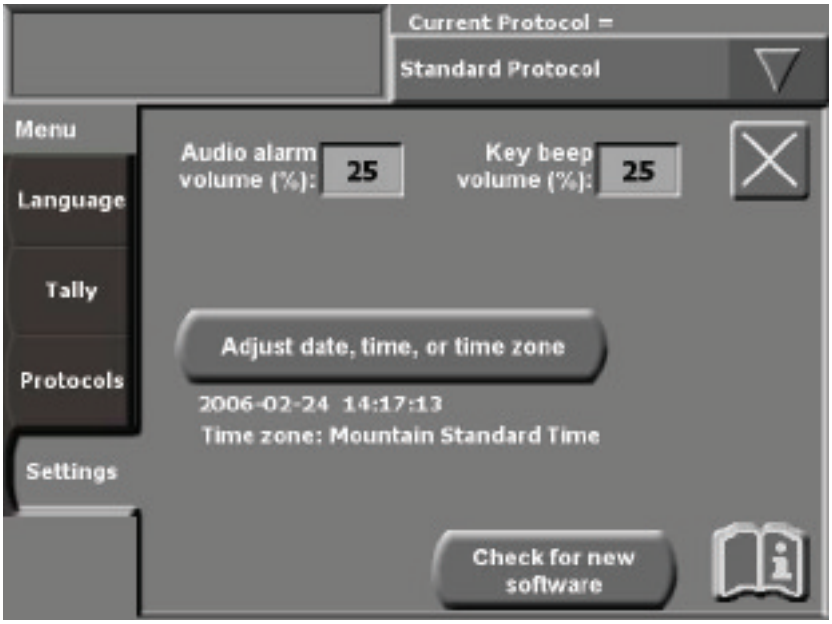


Figure 3-16 "Settings" tab of the Menu Screen

"Audio alarm volume (%)"

To change the volume of the audio alarms sounded by the *Angel® cPRP System*, touch the "Audio alarm volume (%)" parameter box. This will highlight the box and display the arrow buttons. Touch the up and down arrow buttons to increase and decrease the volume of audio alarms. Audio alarms cannot be muted completely.

"Key beep volume (%)"

To change the volume of the invalid key beeps (the sound emitted when a disabled button on the touch screen display is touched), touch the "Key beep volume (%)" parameter box. This will highlight the box and display the arrow buttons. Touch the up and down arrow buttons to increase and decrease the volume of key beeps. To turn off key beeps, set the volume of this parameter to 0%.

"Adjust date, time, or time zone" Button

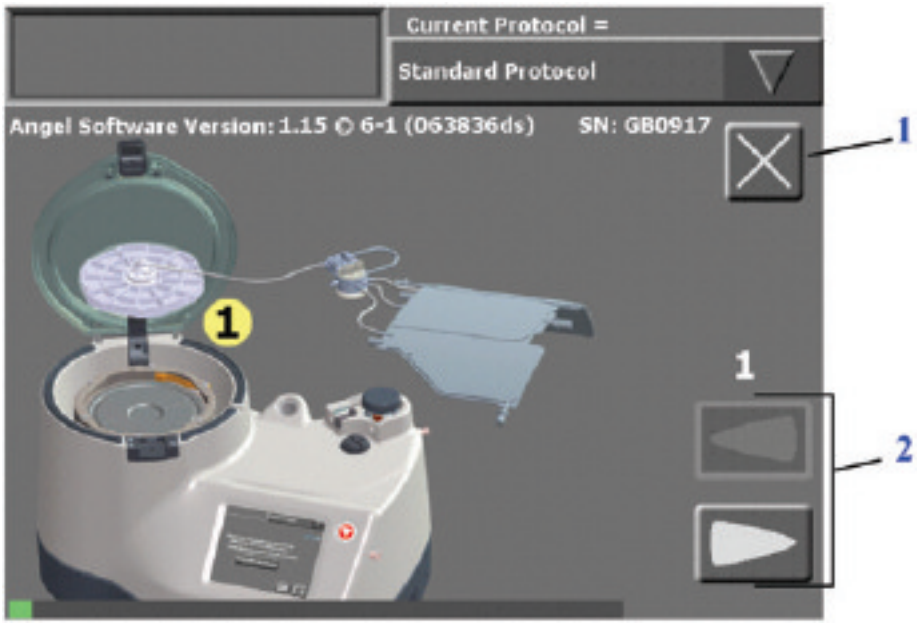
Touching the "Adjust date, time, or time zone" button will display the date and time settings within the "Settings" tab. For instructions on setting the date, time, and time zone, refer to "Setting the Date and Time" on page 1-5.

"Check for new software" Button

Touching the "Check for new software" button will display the New Software Screen on the *Angel® cPRP System's* touch screen display. The New Software Screen is used to check for, download, and install new versions of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System's* software. For details on using the New Software Screen, refer to the section "New Software" in Chapter 6: Routine Care of this manual.

Info Screen

The Info Screen is displayed by touching the Info button from any other screen. The Info Screen displays the *Angel® cPRP System* software version and serial number at the top of the screen, as well as context-sensitive help and/or instructional animations below (see Figure 3-17).



1. Close Button
2. Back Button and Forward Button

Figure 3-17 Info Screen

Close Button

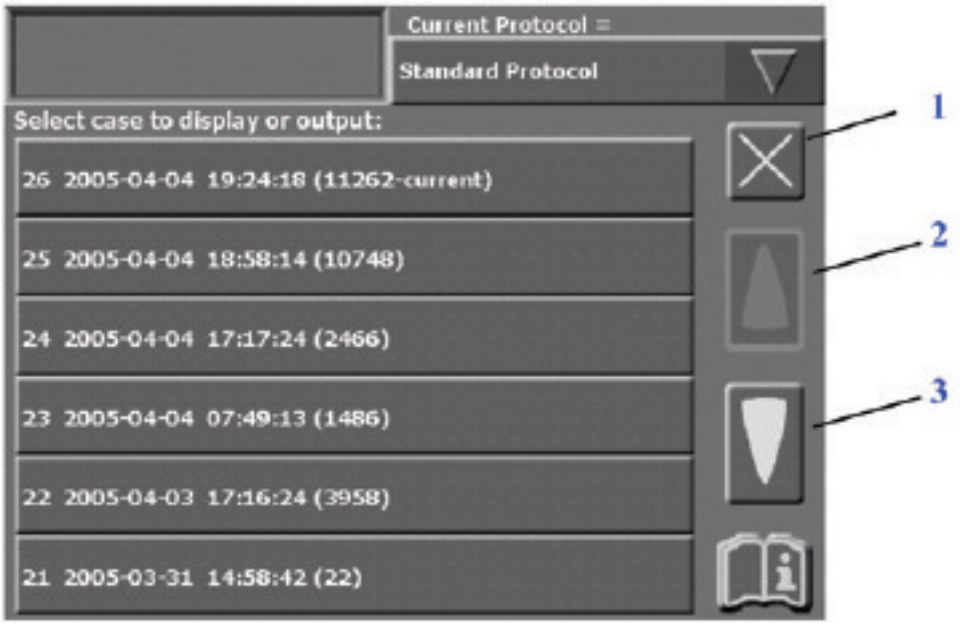
Touching the Close button will close the Info Screen and return you to the previously displayed screen.

Forward/Back Buttons

The Forward and Back buttons are only present within Info Screens that contain animations. These animations are divided into multiple instructional steps. The Forward button advances to the next step, while the Back button replays the current step or skips back to the previous step.

Past Cases Screen

The Past Cases Screen displays a list of past cases that have been run on the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*, allowing those cases to be selected for display or saving (see Figure 3-18).



1. Close Button 2. Up Arrow Button 3. Down Arrow Button

Figure 3-18 Past Cases Screen

Upon display, the Past Cases Screen lists the six most recent cases prior to the current case. For each listed case, the following information is displayed (from left to right):

- the sequential case number automatically assigned by the *Angel® cPRP System*
- the date and time the case was started (from the moment the Start button is touched)
- the number of data lines the case consists of in parenthesis (the current case also contains the text “current” here), and
- the “ID” field if any was entered by the operator (for information on entering the “ID” and other fields to cases, refer to “Entering Optional Case Data Fields” on page 3-6).

To select a case, simply touch it from the touch screen display.

For detailed instructions on saving a selected case, refer to “Saving Case Data” on page 3-5.

Close Button

Touching the Close button will close the Info Screen and return you to the previously displayed End of Case Screen or “Tally” tab.

Up Arrow Button

Touching the Up Arrow button will display the next six newest cases (disabled if there are no cases newer than those already displayed).

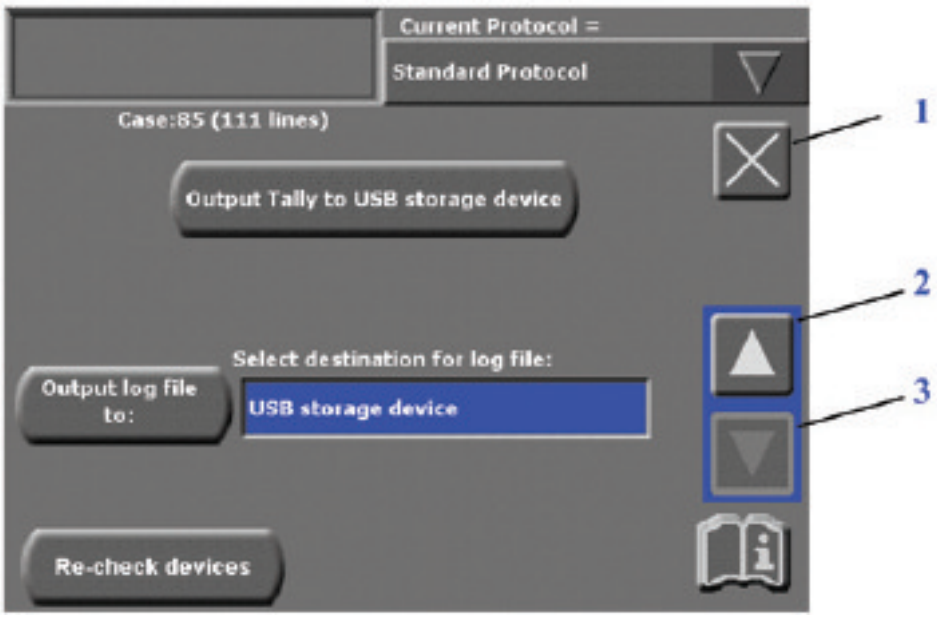
Down Arrow Button

Touching the Down Arrow button will display the next six older cases (disabled if there are no cases older than those already displayed).

Output Screen

The Output Screen is displayed by touching the “Output” button and is used to save either a case tally table or a case log to a connected USB storage device. In addition the “Output” button allows the operator to save a case log to a network server through the *Angel® cPRP System’s* Ethernet port (see Figure 3-19).

For detailed instructions on how to save case tally tables and logs, refer to “Saving Case Data” on page 3-5.



1. Close Button 2. Up Arrow Button 3. Down Arrow Button

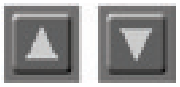
Figure 3-19 Output Screen

At the upper left corner of the Output Screen is displayed the case number, as assigned by the *Angel® cPRP System*, and, in parentheses, the number of data lines the selected case contains.

1. Close Button

Touching the Close button will close the Output Screen and return you to the previously displayed End of Case Screen or "Tally" tab without saving any data.

2-3. Up and Down Arrow Buttons



If the "Select destination for log file:" field is not highlighted, the arrow buttons will not be visible. If the field is highlighted, the arrow buttons will scroll through a list of possible destinations to which the log file for the selected case may be saved.

"Output Tally to USB storage device" button

Touching the "Output Tally to USB storage device" button will commence saving the tally table to a connected USB storage device.

"Output log file to:" Button

Touching the "Output log file to:" button will commence saving case data to the USB storage device or a network server selected by the "Select destination for log file:" field.

"Select destination for log file:" Field

Used to select a USB storage device connected to the *Angel® cPRP System's* USB port or a network server. When touched, the "Select destination for log file:" field will highlight, and the Up Arrow button and Down Arrow button will appear on the right side of the screen. The arrow buttons can then be used to scroll through a list of available destinations.

"Re-check devices:" Button

Touching the "Re-check devices:" button will cause the *Angel® cPRP System* to check for any storage device or network connected to the USB or Ethernet ports. This feature is useful if the desired device was not found, or was not properly connected, at the time the "Output" button was touched.

Stop Button

The Stop button is not required in normal use of the *Angel® cPRP System*. However, if it becomes necessary to stop the processing cycle before it has completed, perform the following:

Press the Stop button mounted on the front of the *Angel® cPRP System*. This will halt the *Angel® cPRP System's* pump, centrifuge, and valve, and will display the Empty Screen on the *Angel® cPRP System's* touch screen display (see Figure 3-20).

Touch the "Empty the set" button to empty the variable volume separation chamber. The variable volume separation chamber must be empty in order to remove the disposable set from the machine.

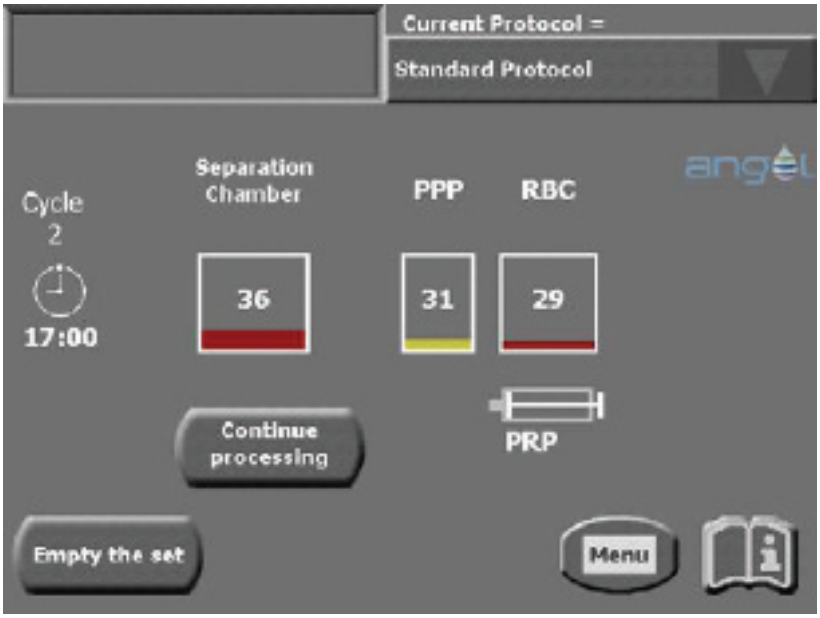


Figure 3-20 Empty Screen

"Continue processing" Button

Touching the "Continue processing" button continues processing the current cycle without emptying the variable volume separation chamber. If the Stop button was pressed during the blood component collection phase, this button is not active.

"Empty the set" Button

Touching the "Empty the set" button causes (1) the centrifuge to stop and (2) the pump to continue until it empties any residual fluid from the variable volume separation chamber into the whole blood compartment, ending the current cycle. (The variable volume separation chamber must be empty in order to remove the disposable set from the machine.)

Power Loss

If power is lost to the machine and residual blood/bone marrow is in the variable volume separation chamber, follow these steps to safely remove the *Angel*® *cPRP Processing Set* from the machine:

1. Do not remove the pump loop tubing from the pump rotor until the handle on the valve assembly is pointed toward the whole blood compartment port.

   If required, manually turn the handle on the valve assembly to the whole blood compartment port (see Figure 3-21).

1. **Whole Blood Compartment Port**

Figure 3-21 Correct Valve Assembly Handle Position

2. Remove pump loop tubing from the pump rotor to release fluid pressure on the variable volume separation chamber, which will allow the residual blood/bone marrow to flow to the whole blood compartment of the three-compartment reservoir bag.

3. After the blood or mixture of blood and bone marrow has emptied from the variable volume separation chamber into the whole blood compartment, remove the disposables from the machine (see Step 5 on Page 3-4).

Chapter 4: Programability Option

PRECAUTION

The user of the Angel® Concentrated Platelet Rich Plasma (cPRP) System is responsible for the monitoring of the system performance when using custom protocols.

Creating Custom Protocols

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* ships with a single Standard Protocol to separate the whole blood or mixture of blood and bone marrow into red cells, PPP and PRP. The parameters of the Standard Protocol have been extensively tested and optimized to produce reproducible results. However, by selecting the “Protocols” tab of the Menu Screen (see Figure 4-1), you may create custom protocols which have different spin speeds and times, or which yield a PRP product containing a different proportion of red blood cells.

During blood separation using the *Angel® cPRP System* Standard Protocol, the anticoagulated whole blood or mixture of blood and bone marrow is pumped into the *Angel® cPRP System’s* spinning variable volume separation chamber. The red blood cells, the heaviest elements of the blood, are separated from the lighter elements, the plasma and platelets, through centrifugation. The *Angel® cPRP System* Standard Protocol uses a two-phase spin cycle consisting of a hard spin and a soft spin. The Standard cycle varies the RPM and Time for this two-phase spin cycle based on the volume of whole blood/bone marrow processed.
On the custom Protocol screen the Spin 1 and Spin 2 values for RPM and Time can be changed.

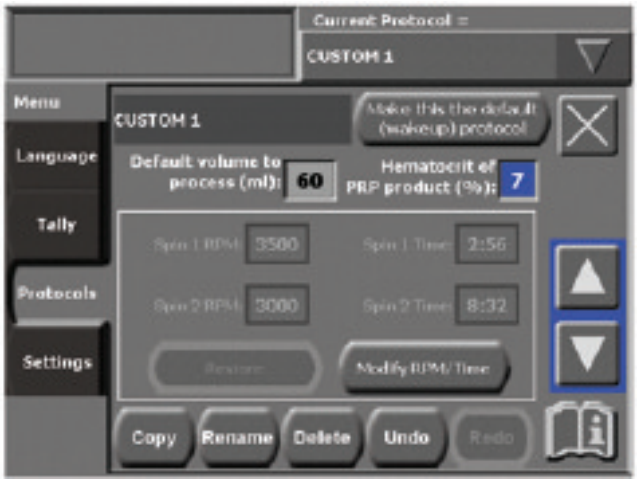
The first product that is collected after the two-phase cycle is complete is the PPP. The PPP is pumped from the spinning variable volume separation chamber into the PPP compartment. When the sensor of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* senses the presence of the PRP layer, the Rotating Valve changes position and directs the PRP product to the PRP syringe plus an additional volume of RBC. The additional volume of RBC maximizes the recovery of platelets. At the end of the PRP collection phase, the Rotating Valve changes position to the RBC compartment and empties the remaining volume.

If the PRP volume collected is diluted to a volume equal to approximately 10% of the processed blood/bone marrow volume the *Angel® cPRP System* Standard Protocol will yield a product with approximately a 7% hematocrit. The Protocol screen allows the creation of a custom protocol for increased or decreased volumes of RBC volume in the final PRP product.

Since young platelets extend into the RBC layer, a change in volume of RBC in the final PRP product will also change the final concentration of platelets in the PRP product.

Changes in the Spin 1 and Spin 2 RPM and Time may also change the concentration of platelets in the final PRP product. The change in concentration and collection of platelets from the *Angel® cPRP System* using a custom protocol rests solely with the operator of the *Angel® cPRP System*. The operator of the *Angel® cPRP System* should be knowledgeable in the methodology of blood component separation prior to operating a custom protocol.

The *Angel® cPRP System* provides additional system flexibility through the use of custom protocols in an effort to address the needs of the experienced clinician. Variation in blood parameters may affect the collection of PRP. Custom protocols provide the experienced user with the ability to adjust the centrifugation cycle to meet these possible variations. Changes in the default processing volume and hematocrit of the final PRP product are common custom protocols that are created. Custom protocols that have changes in RPM and Time should only be created by those knowledgeable in the methodology of blood component separation.



For a complete description of the "Protocols" tab of the Menu Screen, read "The Protocols Tab" on page 4-6.

Figure 4-1 The "Protocols" tab

Entering Values and Text

Before attempting to create a new protocol, you should familiarize yourself with the controls for making changes.

Generally, if you need to change values (such as the default volume to process), you will use the Up arrow button and the Down arrow button, shown above, but also labeled in Figure 4-3.

When you reach a point where text changes are needed, you will use the keyboard screen, illustrated in Figure 4-2.

Current Protocol=
Standard Protocol 2
Type in new protocol name, then touch Enter to save
Backspace
1 2 3 4 5 6 7 8 9 0
Q W E R T Y U I O P
A S D F G H J K L ;
Alt Z X C V B N M , -
Caps & Numbers
Space
Clear
Enter

Figure 4-2 The Keyboard Screen (Protocol Name)

Creating a New Protocol

Follow these steps to create a new protocol:

1. Choose the base protocol (currently selected protocol) from the Protocol pull-down button. You will duplicate the base protocol in order to create the new protocol.

   If you have several available protocols already, choose the one whose parameters are closest to what you desire for the new protocol. If no custom protocols exist on the machine, you must choose the Standard Protocol.

2. Touch the copy button. This will duplicate the protocol you selected in step 1, and will append to its name, numeric value.

3. Touch the Rename button to rename the newly created protocol to a more useful name. Touching the Rename button will display the keyboard screen on the *Angel® cPRP System's* touch screen display (see Figure 4-2).

4. Type in the new name for the protocol.

5. When finished, touch "Enter" to save the new name and return to the "Protocols" tab.

6. Make any desired changes to the protocol parameters.

   Note: Any changes are automatically saved.

7. It is recommended that most protocol changes concern only "Default volume to process" and "Hematocrit of the PRP product" (the two topmost fields).

8. However, if the user needs to change more advanced values, the user may:

   a. Touch the "Modify RPM/Time" button so that the RPM and Spin Time parameters are modifiable. Depending on which protocol you copied, this step may not be necessary.

   b. Touch a parameter box to activate it; this will highlight both the parameter and the arrow keys.

   c. Use the arrow keys to change the value of the parameter.

   d. Any changes will automatically be saved.

9. Once you have set all of the protocol parameters to your desired values, touch the "Make this the default (wakeup) protocol" button if you want the protocol you just created to be the wakeup protocol (power up protocol).

10. Touch the Close button to return to the previously displayed screen.

Editing the Parameters of a Protocol

Follow these steps to edit the parameter values of an existing custom protocol. Note that the Standard Protocol cannot be edited.

1. From the Protocol pull-down button, select the protocol you wish to edit.
2. Make the changes to the protocol parameters as desired.
    a. Touch the “Modify RPM/Time” button if it is enabled so that the RPM and Spin Time parameters are modifiable. If the “Modify RPM/Time” button is disabled, then the RPM and Spin Time parameters can already be edited.
    b. Touch a parameter box to activate it; this will highlight both the parameter and the arrow keys.
    c. Use the arrow keys to change the value of the parameter.
    d. Any changes will automatically be saved.
3. Touch the Close button to return to the previously displayed screen.

Restoring the Parameters of a Protocol

The values of the RPM and Spin Time parameters for any custom protocol may be restored to the recommended Standard Protocol algorithm settings at any time. These are the values used for the Standard Protocol, and are determined by the selected volume of whole blood or blood mixed with bone marrow to process. As the volume is changed, the RPM and Spin Time parameters are changed to optimize platelet collection.

To restore the parameters of a protocol, follow these steps:

1. From the Protocol pull-down button, select the protocol you wish to restore.
2. Touch the “Restore” button.
3. Touch the Close button to return to the previously displayed screen.

Renaming a Protocol

Follow these steps to rename an existing custom protocol. Note that the Standard Protocol cannot be renamed.

1. From the Protocol pull-down button, select the protocol you wish to rename.
2. Touch the Rename button. Touching the Rename button will display the keyboard screen on the *Angel® cPRP System’s* touch screen display (see Figure 4-2).
3. Use the “Backspace” button to edit the previous name, or touch the “Clear” button, located at the bottom of the Keyboard Screen, to clear the old name and type in the new name for the protocol.

You may exit the Keyboard Screen without causing any changes to take effect at any time by touching the Close button located at the upper right corner of the screen.

4. When finished, touch “Enter” to save the new name and return to the “Protocols” tab.

5. Touch the Close button to return to the previously displayed screen.

Changing the Wakeup Protocol

Follow these steps to set a protocol as the wakeup protocol (selected at power-up). The wakeup protocol will be the selected protocol by default whenever the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is turned on.

1. From the Protocol pull-down button, select the protocol you wish to set as the wakeup protocol.

2. Touch the “Make this the default (wakeup) protocol” button.

3. Touch the Close button to save the protocol and return to the previously displayed screen.

Deleting a Protocol

Follow these steps to delete an existing custom protocol. Note that the Standard Protocol cannot be deleted.

1. From the Protocol pull-down button, select the protocol you wish to delete.

2. Touch the delete button. The protocol will be deleted and will no longer be available from the Protocol pull-down button.

3. Touch the Close button to return to the previously displayed screen.

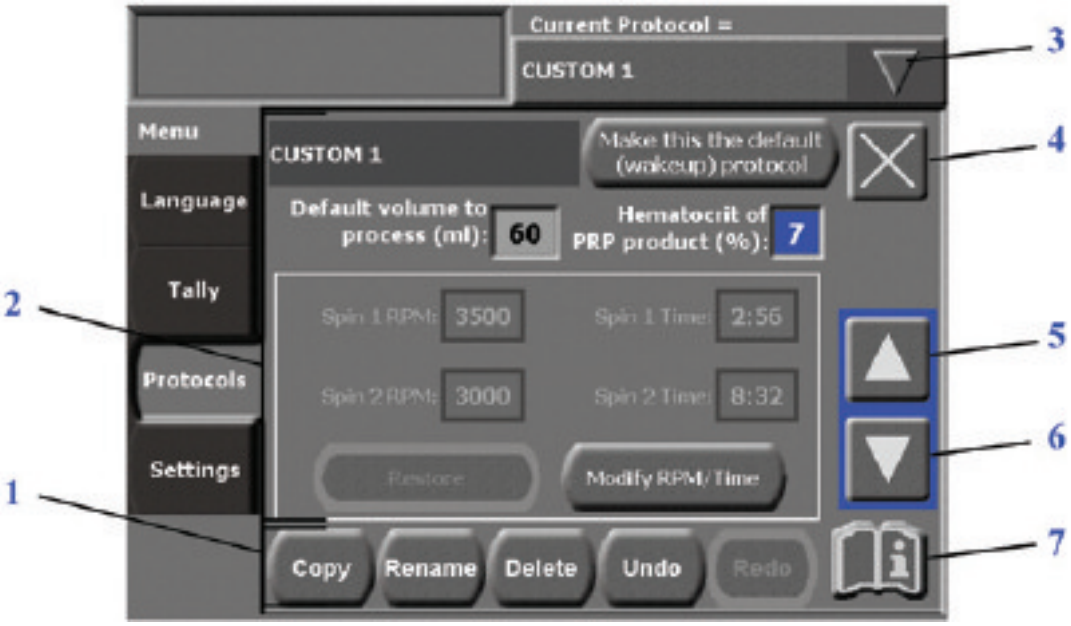
The Protocols Tab

The “Protocols” tab of the Menu Screen allows you to create a custom protocol based either on the Standard Protocol or an already existing custom protocol. To access the “Protocols” tab, touch the Menu button from the Start Screen, and then touch the “Protocols” tab.

The “Protocols” tab is organized with the following, starting at the top:

- the name of the current protocol
- the “Make this the default (wakeup) protocol” button (unless the selected protocol is already the wakeup protocol, as is the case in Figure 4-3)
- the Close button
- the six protocol parameters (with the four RPM and Spin Time parameters within a box)

- Up and Down arrow buttons
- A row of buttons for manipulating the protocol name (copy, delete, rename), undoing changes, redoing changes, and getting contextual information (see Figure 4-3)



1. Protocol buttons
2. Protocol Parameters
3. Protocol pull-down button
4. Close button
5. Up arrow button
6. Down arrow button
7. Info button

Figure 4-3 "Protocols" tab of the Menu Screen

1. Protocol Buttons

Copy Button

Touching the copy button will duplicate the current protocol. This is the only way to create a new protocol. The newly created protocol will have a number prefixed to its name. Touch the Rename button to rename the copy of a protocol.

Rename Button

Touching the rename button will display a keyboard on the touch screen display. Please refer to the illustration in Figure 4-2. Type in the name you wish the protocol to have, and then touch "Enter" to save and return to the "Protocols" tab.

Delete Button

Touching the delete button deletes the current protocol. Once deleted it will no longer be available from the Protocol pull-down button.

Undo/Redo Buttons

Touching the undo button will undo your last action (such as changing the value of a protocol parameter or renaming a protocol). Touching the redo button will redo the last action you have reverted with the undo button. You may undo and redo up to ten different actions.

2. Protocol Parameters and Buttons

The protocol parameters consist of the six values.

Touching a parameter will highlight both the parameter and the up and down arrow buttons. Use the arrow buttons to change the value of the selected parameter.

Every value has a maximum and minimum value, and you will be unable to set the values beyond those.

Default volume to process (ml)

This protocol parameter sets the default volume of whole blood or mixture of blood and bone marrow to process in a single cycle.

Hct of PRP product (%)

This protocol parameter sets the amount (%) of Hematocrit contained in the PRP product of a case. This value is based on a harvest of PRP (including PPP dilution) equivalent to 10% of the whole blood or mixture of blood and bone marrow volume processed.

Spin 1 RPM

The separation process consists of two spin cycles in the centrifuge. This protocol parameter sets the speed (RPM) of the centrifuge during the first centrifuge spin cycle.

Spin 1 Time

This protocol parameter sets the time (minutes:seconds) of the first centrifuge spin cycle.

Spin 2 RPM

This protocol parameter sets the speed (RPM) of the centrifuge during the second centrifuge spin cycle.

Spin 2 Time

This protocol parameter sets the time (minutes:seconds) of the second centrifuge spin cycle.

Current Protocol

The name of the current protocol is displayed at the top right of the “Protocols” tab. Any changes made to the protocol parameters will affect the current protocol after 3 seconds.

“Make this the default (wakeup) protocol” Button

Touching the “Make this the default (wakeup) protocol” button will set the current protocol as the wakeup protocol. Whenever the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is turned on, the wakeup protocol will be used by default.

“Modify RPM/Time” Button

Touching the “Modify RPM/Time” button will allow the four RPM and Spin Time parameters to be modified. Once touched, it will become disabled and the “Restore” button will become enabled.

“Restore” Button

Touching the “Restore” button will restore the values of the four RPM and Spin Time parameters to the recommended Standard Protocol values. Once touched, it will become disabled, the four RPM and Spin Time parameters will become disabled, and the “Modify RPM/Time” button will become enabled.

3. Protocol Pull-Down Button

The name of the currently loaded protocol is displayed to the left of the Protocol pull-down button. Touching the Protocol pull-down button will display a list of available protocols; touching the Protocol pull-down button a second time collapses the list. Touch a protocol’s name in the list to select it as the current protocol which you can then edit, rename, or copy.

4. Close Button

Touching the Close button will exit the Menu Screen, returning to the previously displayed screen.

5-6. Up and Down Arrow Buttons

Touch the Up Arrow button and Down Arrow button to increase and decrease, respectively, the value of the currently selected protocol parameter. Changes are saved automatically.

7. Info Button

Touching the Info button will bring up an Info Screen containing contextual help. Touching the Close button from the Info Screen will return you to the “Protocols” tab displayed screen.

Chapter 5: Troubleshooting

The procedures outlined below are intended to help you identify and correct alarms and other conditions that may occur during operation of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*.

Alarms and Notifications

Alarm icons appear as buttons in the alarm area of the *Angel® cPRP System's* touch screen display. Touching an alarm icon will display the Info Screen containing description and response information for that alarm. That information is also presented in the table below. Some alarms have corresponding instructional videos associated with them which can be viewed from the Info Screen by touching the Movie icon at the lower-right corner of the screen.

Name	Icon	Description	Response
Air during empty		If air is unexpectedly detected in the line during the empty phase of a processing cycle, then the pump is paused and the Air during empty alarm is sounded.	Check for breaks or occlusions in the line and verify pump header is loaded. If none are found, then you may continue processing by touching the green resume button.
Centrifuge overspeed		If the centrifuge speed is detected to be faster than commanded, the Centrifuge overspeed alarm is sounded.	This alarm indicates a hardware failure. If it does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.
Centrifuge underspeed		If the centrifuge speed is detected to be slower than commanded, the Centrifuge underspeed alarm is sounded.	This alarm indicates a hardware failure. If it does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.

Name	Icon	Description	Response
Insufficient fill		The insufficient fill alarm is triggered if air is detected before the desired amount of whole blood or mixture of blood and bone marrow has been pumped into the variable volume separation chamber. Along with the alarm, two buttons are displayed on the Run Screen: the “Process” button and the “Continue Filling” button.	If more than 40 ml of blood or mixture of blood and bone marrow has been pumped into the variable volume separation chamber, you may process it by touching the “Process” button. Or, if available whole blood/bone marrow is available in the whole blood compartment and you wish to continue filling to the desired volume, check to make sure there are no breaks or occlusions in the line and then press the “Continue Filling” button to continue the cycle.
Lid latch		If the latch is detected to be unlatched after the Start button is pressed, the centrifuge is stopped and the Lid latch alarm is sounded.	This alarm indicates a hardware failure. If it does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.
Lid open	yellow red	If the lid is open *before* the Start button is pressed, the yellow icon appears, prompting you to close the lid properly. If the lid opens *during* the cycle, the red icon appears (and the centrifuge stops until the problem is corrected).	Close the lid cover. Ensure tubing is not caught between lid and body of the machine.

Name	Icon	Description	Response
Light sensor calibration sensor		The Light sensor calibration failure alarm is displayed if the platelet sensor is not able to calibrate itself. Three reasons for this are that (1) the user has not loaded the disposable set correctly, (2) the platelet sensor is dirty, or (3) the platelet sensor is too close to an external light source.	If the disposable set is not yet installed, install it according to the instructions in Chapter 2: Installing the Disposables. Make sure that the platelet cuvette is securely in place, and that the valve assembly is properly mounted. Ensure that the platelet sensor is at least 8 feet (1 meter) from all external light sources. If the alarm is still present, clean the platelet sensor then reinstall the disposable set. (Please see the "Note" on 6-8)
Machine temp		If the *Angel*® *Concentrated Platelet Rich Plasma (cPRP) System*'s temperature is detected to be unacceptably high, the Machine temp alarm is sounded.	Power down the *Angel*® *cPRP System* for a short time before any further processing. If this alarm does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.
Plate locking error		If the separation chamber plate is improperly attached to the centrifuge adapter, this alarm sounds.	Turn separation chamber clockwise until position indicator snaps into place. Touch the Movie icon to see an animation which demonstrates how to properly load and lock the separation chamber plate.
PPP bag full		If more than 300 ml of fluid has been pumped into the PPP Compartment of the three-compartment reservoir bag, the PPP bag full alarm is sounded.	Empty the PPP Compartment of the three-compartment reservoir bag, and then continue processing.
Pump direction error		If the pump rotation is detected to be in the wrong direction, the Pump direction error alarm is sounded.	This alarm indicates a hardware failure. If it does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.

Name	Icon	Description	Response
Pump overcurrent		If the pump current is detected to be too high, the Pump overcurrent alarm is sounded.	Check to see if the pump rotor is jammed, and clear any obstructions. If this alarm does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.
Pump overspeed		If the pump speed is detected to be faster than commanded, the Pump overspeed alarm is sounded.	This alarm indicates a hardware failure. If it does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.
Pump rotor		If the pump rotor is not engaged, or not turning, the Pump rotor alarm will be sounded.	Remove the pump loop tubing from around the pump rotor. Press the pump rotor down, and turn clockwise until it is engaged. Place the pump loop tubing around the pump rotor.
Pump underspeed		If the pump speed is detected to be slower than commanded, the Pump underspeed alarm is sounded.	This alarm indicates a hardware failure. If it does not resolve itself, contact the Cytomedix, Inc. Customer Service Response Center.
RBC bag full		If more than 400 ml of fluid has been pumped into the RBC Compartment of the three-compartment reservoir bag, the RBC bag full alarm is sounded.	Empty the RBC Compartment of the three-compartment reservoir bag, and then continue processing.
Valve position error		If the valve assembly is detected to be in the wrong position, the Valve position error alarm is sounded. An icon indicating where the valve assembly should be, along with an arrow pointing in the direction it must be moved, is displayed.	The *Angel® cPRP System* will automatically reposition the valve assembly driver to the correct position when you select the green resume button. If that fails, manually turn the valve assembly handle in the direction indicated by the alarm icon.

The following table contains description and response information for text notifications which may be encountered while operating the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*.

Text	Description	Response
Another protocol has this name–will be replaced	The currently displayed protocol name (in the Keyboard Screen) conflicts with an existing protocol. If saved, the existing protocol with that name will be replaced.	If you do not wish any protocol to be overwritten, modify the name so that it is unique.
Bad protocol: xxxxxx	The given protocol is corrupt and cannot be used.	The *Angel® cPRP System* will automatically select the default protocol for use. If a different protocol is desired, select it from the Protocol pull-down button. The bad protocol will have to be recreated before it can be used.
Copy failed!	An attempt to copy a protocol has failed.	Try copying the protocol again.
Corrected invalid protocol: xxxxxx	The given protocol was detected to be invalid.	No response is needed, the *Angel® cPRP System* was able to automatically correct the protocol.
Delete failed!	An attempt to delete a protocol has failed.	Try deleting the protocol again.
Download failed!	The download of a software update has failed.	Try downloading the software again. If the failure persists, use a different download source or contact the Cytomedix, Inc. Customer Service Response Center.
Hardware does not support this version of software!	The operator has tried to install a software version which is not supported by the current hardware.	Select a previous version of software which is compatible with the current hardware for installation.
Hardware malfunction!	A hardware malfunction has occurred.	Cycle the machine power off and then on. If the problem persists, contact the Cytomedix Inc, Customer Service Response Center.
Installation failed!	Installation failed while downloading new software.	See “Troubleshooting the Software Update Process” on page 5-8 for troubleshooting steps.
Insufficient memory to load this version of software!	The operator has tried to install a software version which is not supported by the current hardware.	Select a previous version of software which is compatible with the current hardware for installation.
No destination found!	The *Angel® cPRP System* is not connected to a valid destination or the destination cannot be reached.	If you wish to output a log file to an external destination, refer to the section “Troubleshooting the Save Process” on page 5-8 for troubleshooting steps.

Text	Description	Response
No software updates found!	No software updates were found.	See “Troubleshooting the Software Update Process” on page 5-8 for troubleshooting steps.
No USB storage device found!	The *Angel® cPRP System* does not detect any connected USB storage device.	If you wish to output tally data or a log file to a USB storage device, refer to the section “Troubleshooting the Save Process” on page 5-8 for troubleshooting steps.
Output failed!	Output failed while attempting to save tally data.	Refer to the section “Troubleshooting the Save Process” on page 5-8 for troubleshooting steps.
Save failed!	Output failed while attempting to save case log file. Or a custom protocol could not be saved.	Refer to the section “Troubleshooting the Save Process” on page 5-8 for troubleshooting steps.
Past case data lost!	Some or all of the data for past or current cases has been lost.	No response necessary. Past case data may not be recovered.
Powerfail protocol not found: xxxxxx	A powerfail has occurred, and the given protocol cannot be found.	The *Angel® cPRP System* will automatically select the default protocol for use. If a different protocol is desired, select it from the Protocol pull-down button. The lost protocol may have to be recreated before it can be used.
Power was lost before end of case.	The *Angel® cPRP System* was shut down or lost power before the end of a processing case.	If power was lost in the middle of a cycle, then the set must be emptied. A new cycle or case may then be started.
Redo failed! Undo/redo history cleared.	An attempt to redo a change while creating a protocol has failed.	The undo/redo history has been cleared. A redo command is not possible at this time.
Rename failed!	An attempt to rename a protocol has failed.	Try renaming the protocol again.
Settings lost and were set to default!	The *Angel® cPRP System’s* settings were lost, and the default settings are being used.	If settings other than the default are desired, make changes via the "Settings" tab of the Menu Screen (see “Settings Tab” on page 3-21).
Software update is not valid!	The new software downloaded from the selected source is corrupt.	Try downloading the software again. If the problem persists, download software from a different source.
The software did not start successfully. Turn power off and on. If the problem persists, download software.	An error occurred while the *Angel® cPRP System* was powering on.	Turn power off and then on. If the problem persists, contact the Cytomedix, Inc. Customer Service Response Center.
This version of software is already installed on this machine.	The operator has attempted to install the same software which is already installed on the machine.	Choose a different version of software to install.

Text	Description	Response
Undo failed! Undo/redo history cleared.	An attempt to undo a change while creating a protocol has failed.	The undo/redo history has been cleared. An undo command is not possible at this time.
Wakeup protocol not found: xxxxxx	The given wakeup protocol cannot be found.	The *Angel® cPRP System* will automatically select the default protocol as the wakeup protocol. If a different protocol is desired, select it from the Protocol pull-down button, and then set it as the wakeup protocol from the "Protocols" tab of the Menu Screen.

Troubleshooting the Save Process

If you receive the error messages “No destination found!”, “No USB storage device found!”, “Output failed!”, “Save failed!”, or encounter other difficulties while attempting to save case data, try the following:

- Ensure the USB storage device or Ethernet cable is properly connected to the correct port on the left side of the machine. If you are having difficulties locating the port, see “*Angel® Concentrated Platelet Rich Plasma (cPRP) System* Components” on page 1-2.
- Once you have fixed any connection problems, touch the “Re-check devices” button from the Output Screen. The *Angel® cPRP System* should now be able to find the appropriate device, and the saving process should be successful.
- If an Output Screen becomes unresponsive, cycle the machine power off and then on to correct error condition.

If you continue to experience difficulty, contact the Cytomedix, Inc. Customer Service Response Center.

Troubleshooting the Software Update Process

If you receive the error messages, “Installation failed!” “No software updates found!” or encounter other difficulties while attempting to install new system software from the New Software Screen, try the following:

- Ensure the USB storage device or the Ethernet cable is properly connected to the correct port on the left side of the machine. If you are having difficulties locating the port, see “*Angel® Concentrated Platelet Rich Plasma (cPRP) System* Components” on page 1-2.
- If you are attempting to update software from a USB storage device, ensure that the device has a valid version of the *Angel® cPRP System* software on it.
- Once you have fixed any connection/network problems, touch the “Re-check sources” button from the New Software Screen. The *Angel® cPRP System* should now be able to find valid software versions from the desired source.

If you continue to experience difficulty, contact the Cytomedix, Inc. Customer Service Response Center.

Chapter 6: Routine Care

To prolong equipment life and to provide maximum system performance, the routine care procedures identified in this section should be followed.

It is presumed that the person(s) using this manual have thoroughly read and understand the precautions associated with the use of this device. Please refer to the section entitled “Before You Get Started” for specific precautions that apply to routine maintenance of the equipment. Precautions have been restated in this chapter where applicable.

PRECAUTION

Due to the possibility of operator exposure to blood-borne pathogens (such as HIV, hepatitis viruses, bacteria, etc.), Universal Precautions for blood-borne pathogens should be practiced.

New Software

Periodically, new versions of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System’s* software may be released which allow for better system performance or new features. New versions of software can be downloaded and installed from the New Software Screen. For a detailed explanation of the New Software Screen, read “New Software Screen” on page 6-6.

New versions of the system software may be downloaded from a USB storage device connected to the *Angel® cPRP System’s* USB port.

In addition to updating the system software, it is possible to download and install an earlier system version.

Follow these steps to install new software on the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*:

1. Connect a USB storage device containing a valid software version, and/or ensure that the *Angel® cPRP System* is connected to a valid network via the Ethernet port.

2. Access the New Software Screen:

    a. Touch the Menu button from any screen to display the Menu Screen.

    b. Touch the “Settings” tab from the Menu Screen.

    c. Touch the “Check for new software” button located at the bottom of the “Settings” tab.

    Note: The “Check for new software” button is disabled during processing. Finish any active cycle and empty the set before attempting to install new software.

    The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* will now check for software on any connected USB storage device or network. While it searches, the text “Searching for software sources. Please wait…” will

appear on the screen. If one or more versions of system software is found, the New Software Screen will appear (see Figure 6-5).

Note: If no software is found on any connected USB storage device or network, then the text “No software updates found!” will be displayed on the screen. If this happens, consult “Troubleshooting the Software Update Process” on page 5-8.

By default, the most recent software version is selected and displayed in the “Select software update source:” field.

3. Select the source from which you wish to download the new software version. Navigate the list of available sources and software versions using the Decrement button and Increment button. If you wish to install the most recent version of software from the available sources, then do not do anything at this step.

4. Touch the “Download software from this source” button.

   You will now be prompted to enter the unlock code for the selected software version (see Figure 6-1). The software unlock code is available from the manufacturer.

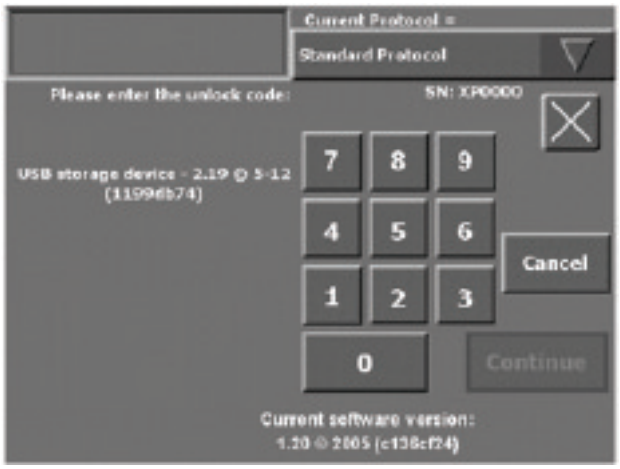


Figure 6-1 Unlock Code Screen

5. Use the keypad on the touch screen display to enter the unlock code.

   When the correct unlock code has been entered, the “Continue” button will become enabled. You may touch the “Cancel” button to return to the New Software Screen without entering an unlock code.

6. Touch the “Continue” button.

   The selected software version will now be copied to the *Angel® cPRP System’s* temporary memory and validated. Three successive progress bars monitor each stage of this process: checking for updates, copying, and finally validating the downloaded files.

   Once the new software version has been copied to the *Angel® cPRP System’s* and validated, the Software Validated Screen is displayed (see Figure 6-2).

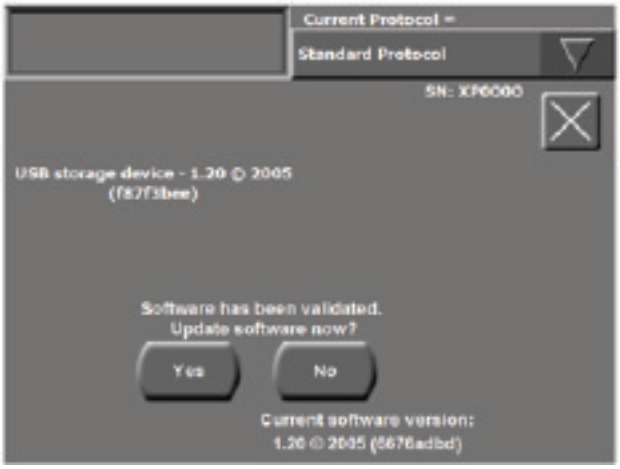


Figure 6-2 Software Validated Screen

7. To continue with the installation, touch the “Yes” button from the Software Validated Screen. Touching the “No” button will cancel the installation without affecting the current system software.

   Next you will be prompted with the Install Screen (see Figure 6-3).

WARNING: DO NOT SHUT OFF POWER during the installation process, or the machine may no longer be useable!
Are you ready to install this software version on this machine?
1.20 © 2005 (f87f3bee)
(Source: USB storage device)
Yes
No

Figure 6-3 Install Screen

   The Install Screen displays the software version you wish to install (as well as the source it has been copied from in parenthesis), and two buttons for final confirmation.

   If you decide you do not wish to install a new software version, touch “No” from the Install Screen and you will be returned to the current *Angel*® *cPRP System* software without any changes to the system occurring.
   If the installation is successful, a “Continue” button is displayed on the Install Screen.

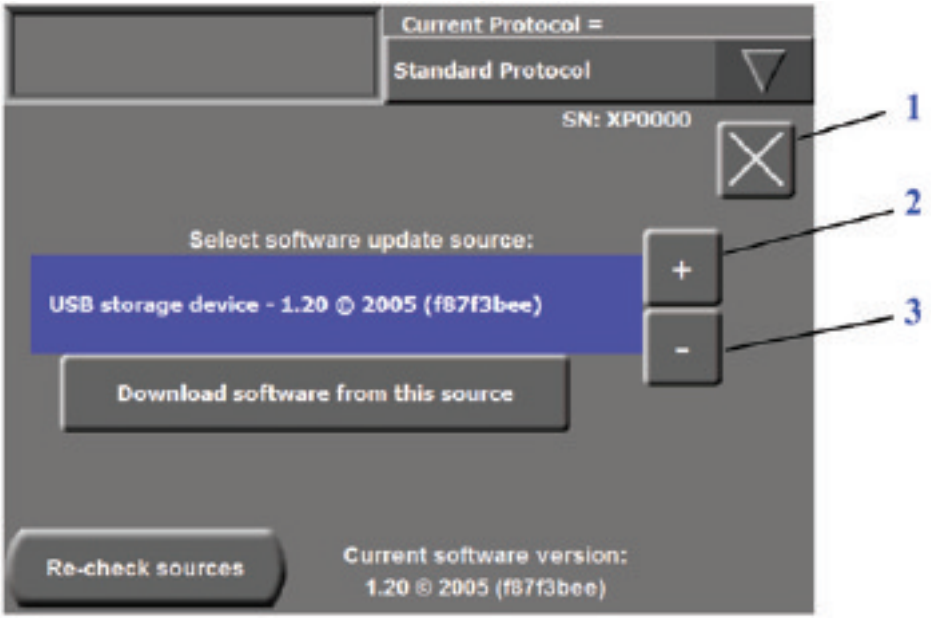
9. Touch the “Continue” button to complete the software installation.

   Wait while the installation process completes. This may take several seconds. Do not shut off the *Angel*® *cPRP System’s* power during this time.

Note: If “Installation failed” is displayed, the machine will restart and will return to the New Software Screen.

New Software Screen

The New Software Screen is displayed by touching the “Check for new software” button from the “Settings” tab of the Menu Screen. It is used to select, download, and install new versions of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System’s* software (see Figure 6-4).



1. Close button
2. Increment button
3. Decrement button

Figure 6-4 New Software Screen

The *Angel® cPRP System’s* serial number is displayed in the top right corner of the New Software Screen.

1. Close Button

Touching the Close button will close the New Software Screen and display the Menu Screen.

2-3. Increment and Decrement Buttons

Touching the Increment button and Decrement button scroll through the list of available versions, and their sources, as displayed in the “Select software update source:” field. The selected version may be installed by touching the “Download software from this source” button.

"Select software update source:" Field

Displays the currently selected software source and version. The Increment button and Decrement button may be used to select newer or older software versions. The most recent version is selected by default when the New Software Screen is displayed.

"Download software from this source" Button

Touching the "Download software from this source" button to begins the installation process for the selected software version. When the button is touched, the selected software version is copied to the *Angel® cPRP System's* temporary memory and validated. It is not installed, however, until the operator confirms the installation from the Install Screen. Refer to "New Software" on page 6-3 for details.

"Re-check sources" Button

Touching the "Re-check sources" button will cause the *Angel® cPRP System* to check for any storage device or network connected to the USB or Ethernet ports for valid software to install. Useful if the desired source was not found, or was not properly connected, at the time the "Check for new software" button was touched.

Visual Inspection

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* should be inspected periodically for any problems such as bent or broken switches, frayed or twisted power cords, and loose or missing hardware. Discontinue use of the *Angel® cPRP System* if the device displays one or more of the above conditions until the problem is corrected and it has been verified that the device is operating correctly.

Verify that the connectors, located on the exterior of the *Angel® cPRP System*, for Data and Ethernet are intact and are not damaged.

Routine Care

External Surfaces

After each use, clean all surfaces of the *Angel® cPRP System* using a soft cloth and mild detergent or disinfectant according to hospital or center protocol. A mixture of one (1) part household bleach to fifteen (15) parts of water (15:1) works well for most areas.

To prevent possible discoloration or damage to protective panels on the *Angel® cPRP System*, do not use cleaning products such as iodine, Betadine, benzol, zylene, acetone or any other abrasive type of cleaning product.

Particular care should be observed when cleaning the centrifuge lid and the touch-screen on the *Angel® cPRP System*. Do not use abrasive cleaners for these areas.

Note: Clean the platelet sensor using a mild detergent.

PRECAUTION

When cleaning the platelet sensor, do not use bleach, abrasive materials or solvents as they may cause damage to the sensor. Use a mild detergent.

Routinely verify that all air intake areas of the *Angel® cPRP System* are clear of debris and clean as required.

Non-Routine Care

In the event of a fluid (blood) spill, additional cleaning may be required beyond routine cleaning. For example, fluid spills that accumulate in the centrifuge well of the *Angel® cPRP System* require different procedures than spills isolated to the exterior of the machine. This section identifies specific non-routine cleaning procedures for properly cleaning spills.

Cleaning the Centrifuge Well

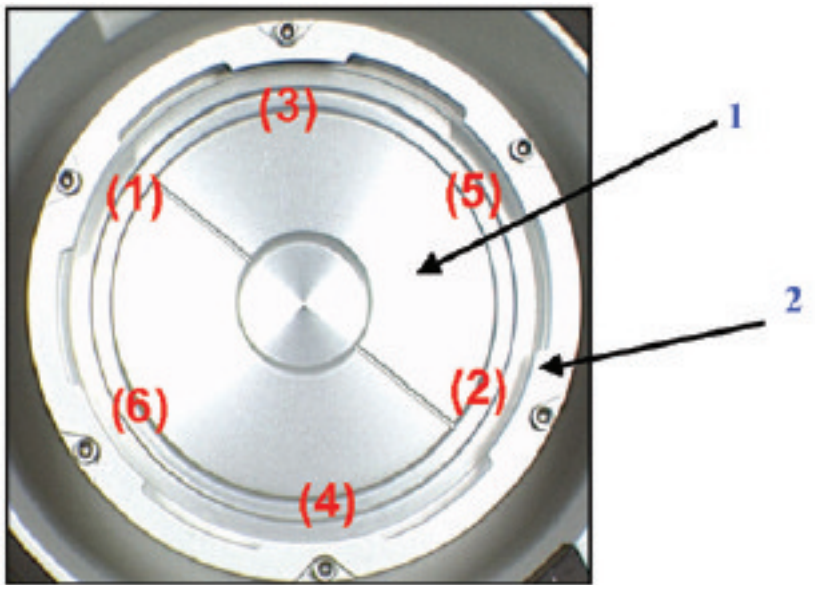
Using a sponge or cloth rinsed in mild detergent, disinfectant or a 15:1 water to bleach solution, absorb and discard any excess fluids that have accumulated in the centrifuge well.

Once the bulk of the fluids have been removed, follow the procedure below to remove, disassemble, clean, reassemble and reinstall the centrifuge adapter plate:

PRECAUTION

Take care not to misplace the screws and springs when disassembling the centrifuge adaptor plate. If springs or screws are misplaced, you may order replacements by contacting the Cytomedix, Inc. Customer Service Response Center.

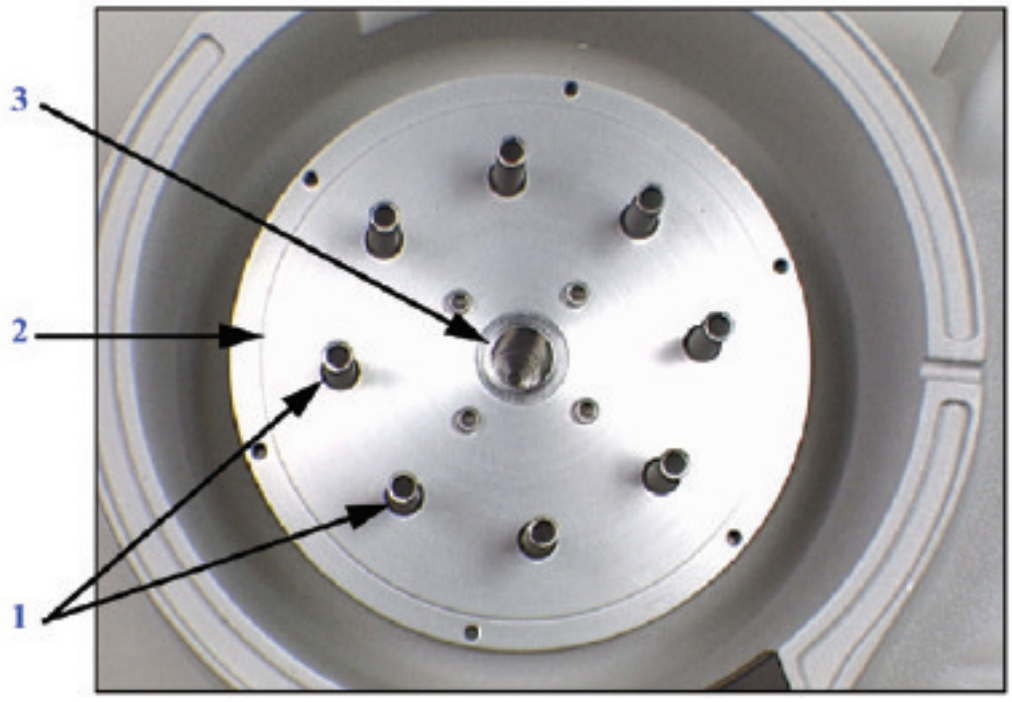
1. Remove the six (6) locking cap screws, in the following way. First completely remove cap screws 1-4, and then alternate between screws 5 and 6, two turns at a time. Set aside the screws for use in reassembly.



1. Spring Plate 2. Adaptor Top

Figure 6-5 Removing the Centrifuge Adaptor Plate

2. Remove the spring plate, taking care not to misplace the springs residing beneath the spring plate. Remove the springs and set aside for reassembly. If needed, remove centrifuge plate by removing the four cap screws that secure the centrifuge plate to the motor spindle.



1. Springs (x8)
2. Centrifuge Plate
3. Spindle

Figure 6-6 Removing the Spring Plate and Springs

3. Using mild detergent, disinfectant or a 15:1 water to bleach solution, clean the top of the adapter base, beneath the adapter base in the well, the spring plate, the adaptor top and rinse the springs and screws to remove any spilled fluids.

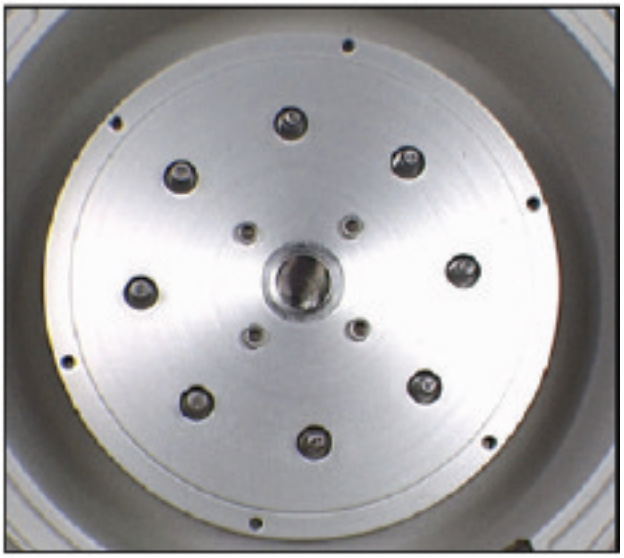


Figure 6-7 Cleaning On and Around the Adaptor Base

4. On completion of the cleaning procedure:

   a. If needed, reinstall the centrifuge plate. Secure the plate to the spindle with cap screws and torque to approximately 20 inch-pounds.

   b. Reinstall the springs over each corresponding dowel pin.

   c. Place the spring plate on the springs and rock/rotate the spring plate until the springs position into the holes on the underside of the spring plate.

   d. Place the adaptor top over the spring plates.

   e. Insert two screws opposite each other and alternately tighten the two (2) screws about 5 turns each time until both screws are hand tight.

   f. Alternately install the remaining 4 screws in order until hand tight.

   g. Torque all screws to 20 inch-pounds following the same alternating pattern.

   h. Press down on the spring plate. It should immediately spring back.

Cleaning the Pump Rotor

1. Remove the pump rotor from the rotor housing by pushing down and turning the rotor counter-clockwise.

Figure 6-8 Removing the Pump Rotor

2. Wipe and rinse the pump rotor to remove any foreign debris and fluids.

3. Using a sponge rinsed in mild detergent, disinfectant or a 15:1 water to bleach solution, absorb any excess fluids that have accumulated in the pump well and wipe clean with a soft, clean cloth.

4. Reinstall the pump into the rotor housing by pushing down and turning the rotor clockwise.

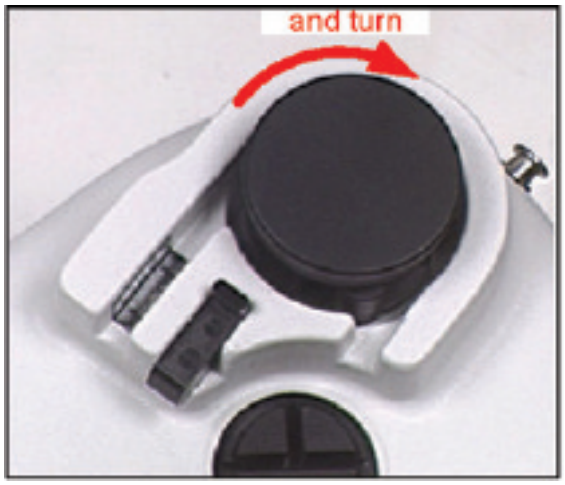


Figure 6-9 Reinstalling the Pump into the Rotor Housing

Preventive Maintenance Requirements

The *Angel*® *cPRP System* is designed to be maintenance free and therefore does not require any Preventive Maintenance. All calibration and operational checks are performed automatically on start-up of the device.

List of Data Integrity Accessories

P/N	Description
020243	MI1005 Baaske-Medical Ethernet Isolator
020244	1.1 MED Baaske-Medical USB Isolator

List of Operator Replaceable Parts

P/N	Description
602 000 000	Centrifuge hardware spare parts (springs, cap screws)
602 000 001	Shipping kit
602 000 002	Pump rotor spare
602 000 003	Centrifuge lid spare
602 000 004	North American power cord spare
602 000 005	Centrifuge stator arm spare

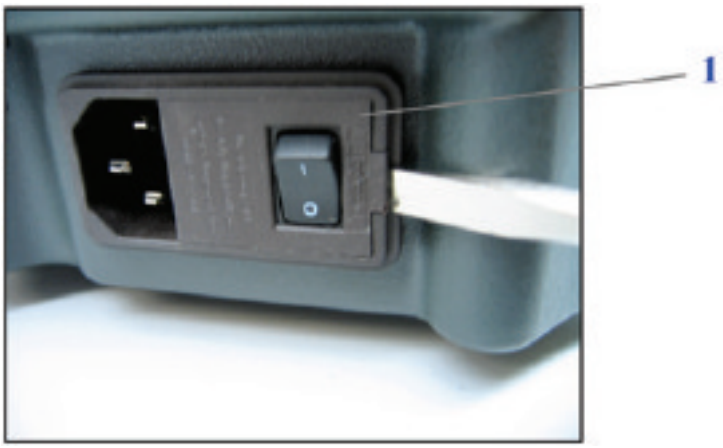
Fuse Replacement

In the event that a fuse fails, follow these steps to replace it. If the replacement fuse fails, there may be an electrical component failure internal to the machine or a problem with the wall current. Contact the Cytomedix, Inc. Customer Service Response Center.

WARNING

To prevent risk of electrical shock, shut OFF power and unplug the system from the electrical outlet before performing cleaning procedures or replacing the fuses.

1. Using a flat screwdriver, pry open the covering on the power switch.



1. Power Switch cover conceals the two fuses

Figure 6-10 Fuse Replacement: Pry Open Cover

2. Once you have opened the cover, the two fuse holders are visible.

Figure 6-11 Fuse Replacement: Slide Out Holders

Note the orientation of the downward arrows on the fuse holder. Pull to remove each holder from the machine.

3. Once you remove the fuse holders, replace the fuses themselves with fuses of identical specification (5X20mm size, 5A 250VAC fast blow).

4. Reverse the removal steps in order to re-install.

Verify that the stator arm is not loose on its pivot pin. It should only rotate up and down with hand pressure and have no side-to-side motion. If the arm is loose, lift it to the raised braking position and locate the cap screw near the base of the stator arm. Using a 9/64 inch hex wrench, tighten the cap screw against the pivot pin.

Chapter 7: Technical Data

Note: No circuit descriptions or component supply lists are included because the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* includes no user-serviceable parts (outside of fuses which are specified on page 6-10).

Specifications

Performance Characteristics

Blood or mixture of blood and bone marrow processing volume per cycle = 40 - 180 ml

Processing time = approximately 15 - 28 minutes

Maximum processing per disposable = 180 ml

Patient hematocrit requirements: 40 ml anticoagulated whole blood or mixture of blood and bone marrow volumes require a patient hematocrit of 30% or greater. The recommended minimum patient hematocrit for anticoagulated whole blood volumes of 50 ml or greater is 28%.

Physical Characteristics

Characteristic	Performance	Condition
Dimension		
Height	30.0 cm (11.8 in)	Nominal
Width	50.3 cm (19.8 in)	Nominal
Depth	35.6 cm (14.0 in)	Nominal
Weight	16.8 kg (37.0 lb)	Nominal
Flow and Speeds		
Process Pump	10 to 60 ml/min	Nominal
Centrifuge	4000 rpm	Maximum

Environmental Limitations

Characteristic	Performance	Condition
Mains Voltages	100 - 240 V~	
Mains Current	5A	Maximum
Line Frequency	50 Hz-60 Hz	
Ambient Operating Temperature	10 to 30 C (50 to 86 F)	
Ambient Operating Humidity	10 to 75%	Non-condensing
Storage Temperature	-20 to 37.7C (-4 to 100 F)	
Storage Humidity	10 to 90%	Non-condensing
Restrictions		Not to be used in an explosive atmosphere

Guidance and manufacturer's declaration – electromagnetic emissions

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	used for domestic Group 1	The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	A	The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings purposes.
Harmonic emissions IEC 61000-3-2	A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-6kV contact +/-8kV air	A	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/-2kV for power supply lines +/-1kV for input / output lines	A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1kV differential mode +/-2kV common mode	A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	A B A B	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* requires continued operation during power mains interruptions, it is recommended that the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.17\sqrt{P}$ $d=1.17\sqrt{P}$ 80MHz to 800MHz $d=2.33\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[i], should be less than the compliance level in each frequency range[ii]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	

Note: At 80MHz and 800MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

i. Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is used exceeds the applicable RF compliance level above, the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Angel® Concentrated Platelet Rich Plasma (cPRP) System*.

ii. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the *Angel® Concentrated Platelet Rich Plasma (cPRP) System.*

The *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Angel® Concentrated Platelet Rich Plasma (cPRP) System* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150kHz to 80MHz $d=1.17\sqrt{P}$	80MHz to 800MHz $d=1.17\sqrt{P}$	800MHz to 2.5GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Classification according to EN 60601-1/IEC601-1

Characteristic	Performance
Protective Class	I
Type	No applied parts
Operation	Continuous Operation

Chapter 8: Warranty

Limited warranty and contractual conditions for Cytomedix, Inc. medical devices

This Limited Warranty is in addition to any statutory rights of the Purchaser pursuant to applicable law.

Warranty Expiration

Cytomedix warrants that all reasonable care has been taken in the manufacture of the Cytomedix™ *Angel® Concentrated Platelet Rich Plasma (cPRP) System,* as required by the nature of the system and the use for which the system is intended. All products are guaranteed for a period of 12 months starting on the date of installation and, in any event, for not more than 13 months starting on the date of dispatch, even when, in this latter case, the period of installation of the equipment is less than 12 months.

For this warranty to be effective, Cytomedix or its authorized representative must be notified of any defects or faults within 8 days from the date of discovery of such defects or faults. Any replacements and/or repairs made to products under warranty shall not be considered an extension of the overall warranty period as agreed above.

Contents and necessary requirements of the warranty

a) Any service rendered under this warranty shall be limited to the repair and/or replacement, in the Cytomedix, Inc. factory, of materials with faults verified and ascertained by Cytomedix. Cytomedix guarantees that the safety of the devices is in no way altered by maintenance and/or repair activities performed by its engineers.

b) Cytomedix shall be responsible for the safety, performance and operation of its products providing that:

   1. Updates, extensions, modifications and repairs are done by authorized Cytomedix personnel;

   2. the electrical system to which the devices are connected conforms to the relevant applicable standards (special care has to be taken for the integrity of the earth conductors and environmental protection circuits) and;

   3. the products are used as indicated in the “OPERATOR’S MANUAL” delivered to the customer together with the equipment (of which this “LIMITED WARRANTY” is an integral part).

c) The warranty does not cover those parts which, by their very nature, are likely to deteriorate.

Cases in which the warranty shall not be effective

Cytomedix assumes no responsibility for any loss, damage, expense, incidents or consequences arising directly or indirectly from the improper use of the Cytomedix *Angel® Concentrated Platelet Rich Plasma (cPRP) System*. Cytomedix hereby emphasizes that users must adhere strictly to the instructions for use of the system and follow all precautions necessary for the correct use of the system.

Cytomedix undertakes to replace any defective component of the Cytomedix *Angel® Concentrated Platelet Rich Plasma (cPRP) System* in the event that such component is defective when shipped by Cytomedix up to the time of delivery to the final user unless such defect has been caused by mishandling by the purchaser or the passage of any expiration date indicated on the packaging.

Warranty for replaced parts

The warranty provided by Cytomedix with respect to repairs or updating of a device no longer under warranty, shall be limited to the replaced parts only, and shall not be effective for no more than three months from the date of replacement.

Availability of spare parts

Cytomedix guarantees spare parts and trained personnel will be available to repair and/or service its devices for a period of 12 months (1 year) from the date each model ceases production.

Technical documentation

a) Cytomedix products are always supplied complete with adequate documentation, including, inter alia, instructions for correct use, identification of replaceable parts and relevant replacement procedures, as well as the list of routine care activities. Other details may concern any disposables needed for correct use of the device.

b) All the documentation and information, drawings and descriptions contained in the manual or, for whatever reason, provided to the user, shall be considered as confidential and as belonging exclusively to Cytomedix. These shall not therefore be revealed, distributed, copied or reproduced by any means and for whatever purpose, nor to be given out for consultation, total or partial, to anyone, without specific prior authorization being formally given by Cytomedix.

c) Cytomedix reserves the right to make, without prior notice, amendments or updates to the contents of previously distributed documentation.

Maintenance contracts

Cytomedix offers its customers “customized” maintenance contracts to meet specific requirements. Interested customers may contact Cytomedix or the local representative/distributor for further details and applicable contractual conditions. Cytomedix guarantees that all maintenance work will be performed by trained personnel, using original spare parts.

Limits to the warranty with regard to product use by the buyer and/or user

Cytomedix warrants that all reasonable care has been taken in the manufacture of the Cytomedix *Angel® Concentrated Platelet Rich Plasma (cPRP) System*, as required by the nature of the system and the use for which the system is intended.

Cytomedix warrants that the Cytomedix *Angel® Concentrated Platelet Rich Plasma (cPRP) System* is capable of functioning as indicated in the current instructions for use when used in accordance with such instructions by a qualified medical professional and before the expiration date indicated on the packaging of any component thereof.

Cytomedix makes no guarantee that: (1) a user of the Cytomedix *Angel® Concentrated Platelet Rich Plasma (cPRP) System* will use the system correctly, or (2) an incorrect diagnosis or therapy and/or the particular physical and biological hematological characteristics of an individual patient, do not affect the performance and effectiveness of the system with damaging consequences for the patient, even though the specified instructions for use have been respected, and Cytomedix hereby disclaims any liability or responsibility for any such consequences resulting therefrom.

Technical safety standards applicable for the purpose of the warranty

a) The safety standards applicable for the purpose of this warranty shall be those enforced in the Country where the device is addressed by the Manufacturer at the time of marketing of such device.

b) In Europe, safety as regards electrical and mechanical hazards, explosions and fires, with respect to medical electrical equipment, is defined by the following harmonized standard:

   EN 60601-1: Medical electrical equipment - Part 1: general requirements for safety which implements the requirements of the International Standard

   IEC 601-1: Safety of medical electrical equipment-Part 1: general requirements issued by I.E.C., International Electrotechnical Committee, and already transposed by C.E.I., Comitato Elettrot ecnico Italiano, such as: CEI 62-5: Apparecchi elettromedicali-Parte 1: nor me generali per la sicurezza

   Such standards apply to medical electrical equipment intended for use by or under the control of qualified personnel in the immediate proximity of the patient and in relation to the patient him/herself (by proximity it is meant the area within 2.5 m from the patient).

c) Each unit manufactured by Cytomedix undergoes safety tests as prescribed by the relevant standard IEC 601.1, the results of which are available from Cytomedix.

d) Any requests for specific measurements of safety parameters different from those above quoted shall be analyzed and assessed by Cytomedix as appropriate and, in the event of these being accepted by Cytomedix, shall be expounded in a specific statement.

Absolute prohibition to amend the conditions of this warranty

The above replaces all other warranties explicit or implicit, written or verbal, including warranties of merchantability and fitness for a particular purpose. No person, including any representative, agent, dealer, distributor or intermediary of Cytomedix or any other industrial or commercial organization is authorized to make any representation or warranty concerning this medical system except as expressly stated herein. Except for the warranties expressly stated herein, Cytomedix hereby disclaims and excludes all other warranties, express or implied, including, without limitation, the implied warranties of merchantability and/or fitness for a particular purpose.

The purchaser undertakes to comply and cause any user to comply with the terms of this Limited Warranty and agrees, in the event of a dispute or litigation with regard to the Cytomedix *Angel® Concentrated Platelet Rich Plasma (cPRP) System*, not to make claims based on any alleged or proposed changes or alterations made to this Limited Warranty by any representative, agent, dealer, distributor or other intermediary of Cytomedix in violation of the terms hereof.

Applicable law and jurisdiction

This Limited Warranty shall be governed by and construed in accordance with the domestic laws of the State of Maryland without giving effect to any choice or conflict of law provision or rule (whether of the State of Maryland or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Maryland.

Any action or proceeding seeking to enforce any provision of, or based on any right arising out of, this Limited Warranty, may be brought only in the courts of the State of Maryland, county of Montgomery, or, if it has or can acquire jurisdiction, in the United States District Court for the District of Maryland, and by your use of the system, you acknowledge your consent to the jurisdiction of such courts (and of the appropriate appellate courts) in any such action or proceeding and waive any objection to venue laid therein. Process in any action or proceeding referred to in the preceding sentence may be served anywhere in the world.

Identification of manufacturer

Please feel free to contact Cytomedix for any further details and/or technical assistance you might require.

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